Performance Report to Congress

# Generic Drug User Fee Amendments

## FY 2025

# Executive Summary

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

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

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

GDUFA III continues to build on previous iterations of the program. The GDUFA III Commitment Letter,[4] agreed to by FDA and industry, includes performance goals intended to enhance the transparency and efficiency of the generic drug review process and to update terminology and negotiated timelines for responding to controlled correspondence. As described in this report, these commitments, and many other elements of the GDUFA III program, have produced success for the generic drug program and, more importantly, for the American people.

This annual report presents both preliminary data on FDA's FY 2025 review performance goals and commitments under GDUFA III and updated data for FY 2023 and FY 2024.

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

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

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

[4] https://www.fda.gov/media/153631/download?attachment.

## Highlighted Achievements – FY 2025

Highlights of FDA's FY 2025 activities are provided below.

*Generic Drug Assessment and Approval Activity Highlights*

In FY 2025, FDA approved 689 abbreviated new drug applications (ANDAs) and tentatively approved 250 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 2025 are displayed on Table 1.

**Table 1. Significant First Generic Approvals for FY 2025**

| Generic Name | Brand Name | Indication | Approval Date |
|---|---|---|---|
| Liraglutide Injection | Saxenda | Chronic weight management | August 2025 |
| Iron Sucrose Injection | Venofer | Iron deficiency anemia in CKD/dialysis | August 2025 |
| Sitagliptin + Metformin XR | Janumet XR | Type 2 diabetes | June 2025 |
| Rivaroxaban | Xarelto | Anticoagulation | May 2025 |
| Siponimod | Mayzent | Multiple sclerosis | April 2025 |

*GDUFA Regulatory Science and Research Highlights*

The GDUFA Regulatory Science and Research Program has consistently fostered early engagement between FDA and the generic drug industry, supported collaboration with generic industry representatives to determine the GDUFA Regulatory Science and Research Priority Initiatives for each future year,[5] 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

[5] 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.

opportunities for better informed engagement following ANDA submission in meetings between FDA and ANDA applicants to discuss scientific matters.

During FY 2025, the GDUFA Regulatory Science and Research Program generated 82 peer-reviewed scholarly articles, 79 external posters related to generic drugs, and 111 external talks presented at national and international scientific and medical conferences.

Although no new grants and contracts were funded in FY 2025, ongoing internal and external research projects continued to advance external research collaborations in areas identified as FY 2025 GDUFA Science and Research Priority Initiatives for generics.[6] These research priorities were established based upon public input during the FY 2024 GDUFA public workshop and comments submitted to the docket for that workshop, as well as upon discussion with generic industry representatives in bi-annual meetings of the GDUFA Industry-FDA Working Group.

Among several notable ANDAs approved during FY 2025, FDA approved the first generic liraglutide injection (referencing Victoza®) on December 23, 2024, marking a significant milestone as the first generic product approved for a once-daily GLP-1 receptor agonist for type 2 diabetes. This approval represents a notable achievement because of the unique scientific challenges associated with developing and demonstrating bioequivalence for this biologically complex synthetic peptide that mimics human GLP-1. Unlike traditional small-molecule generics, liraglutide's peptide structure required sophisticated analytical approaches to accurately characterize its molecular structure and impurity profiles, because differences in structure or impurity profiles of a prospective generic peptide drug compared to the reference listed drug (RLD) may affect biological activity or trigger unwanted immune responses.

The GDUFA Regulatory Science and Research Program's systematic investment in peptide characterization methodologies proved instrumental in enabling this approval. FDA scientists leveraged GDUFA-funded research to develop and apply advanced Nuclear Magnetic Resonance (NMR) techniques specifically designed to support the assessment of oligomeric structures in GLP-1 peptides. This work involved implementing novel analytical tools with enhanced sensitivity for detecting subtle changes in liraglutide's oligomeric structures, enabling more precise characterization comparisons between RLD and test products during analytical similarity assessments. These advanced NMR methodologies also support quality assurance by detecting pH-dependent oligomerization changes that traditional analytical methods might miss, providing a more comprehensive understanding of the peptide's structural behavior under various conditions.

Additionally, GDUFA-funded research contracts with scientists at EpiVax and CUBRC facilitated the development of innovative methodologies for evaluating immunogenicity risks associated with impurities in peptide generics like liraglutide. This collaborative

[6] A detailed description of the FY 2025 GDUFA Science and Research Priority Initiatives can be found at https://www.fda.gov/media/183858/download?attachment.

research effort resulted in novel approaches to assess immunogenic risks for peptide therapeutics and their associated impurities, providing FDA with enhanced scientific tools to evaluate the safety profile of complex generic peptide products.

The impact of this GDUFA-supported research extended beyond the initial Victoza® generic approval. A few months later, on August 27, 2025, FDA also approved the first generic liraglutide injection referencing Saxenda®, a higher-dose formulation of liraglutide indicated for chronic weight management. The same body of GDUFA science and research that facilitated the regulatory assessment and approval of the first generic for Victoza® also supported the regulatory assessment that led to the approval of the first generic for Saxenda®, demonstrating the enduring value and broad applicability of targeted regulatory science investments.

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, 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)[7] during FY 2025. 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. Indeed, during FY 2025, FDA and the CRCG co-hosted five workshops, all of which included faculty from the generic drug industry, academia, and FDA.[8]

Overall, FDA hosted or co-hosted 12 scientific meetings, webinars, and public workshops during FY 2025 to promote transparency through regulatory and scientific outreach and to enhance collaboration and communications through dialogue with academic experts and pharmaceutical industry representatives. These meetings, webinars, and public workshops directly help address scientific challenges and can accelerate the development of generic products, including complex generics. A complete listing of these events is available in section IV of this report.

[7] Information about the CRCG may be found on its website at https://www.complexgenerics.org/.
[8] Additional details about FDA-CRCG events are included in section IV of this report under "GDUFA Regulatory Science and Research Highlights – Outreach Highlights."

*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 2025, FDA issued various policy documents relating to generic drugs, including six guidances for industry (not including product-specific guidances (PSGs)) and two *Federal Register* notices.

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 2025, FDA issued 925 PSGs (49 for complex products). As of September 30, 2025, FDA had published 2,288 PSGs on FDA's Product-Specific Guidances for Generic Drug Development website.[9]

In FY 2025, FDA continued its successful implementation of the law widely known as the "Creating and Restoring Equal Access to Equivalent Samples Act" (or "CREATES" Act")[10] 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 51 Covered Product Authorizations to 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.

In October 2024, FDA published a final guidance for industry entitled *M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms* which provides recommendations for conducting bioequivalence (BE) studies during 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. This is the first International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ( ICH) guidance focusing on harmonized BE standards for generics. In addition, as part of M13A implementation, FDA revised more than 826 draft PSGs for a subset of immediate-release oral drug products to align with M13A. The revised PSGs recommend that ANDA applicants conduct one BE study for products with a non-high

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

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

risk of bioinequivalence due to food effect, under either fasting or fed conditions, rather than conducting two BE studies, one BE under fasting conditions and one BE study under fed conditions.  These guidances help streamline generic drug development globally and support FDA's Drug Competition Action Plan.

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## Acronym List

| | |
|---|---|
| **ANDA** | Abbreviated New Drug Application |
| **AI** | Artificial Intelligence |
| **API** | Active Pharmaceutical Ingredient |
| **BCS** | Biopharmaceutics Classification System |
| **BE** | Bioequivalence |
| **CBER** | Center for Biologics Evaluation and Research |
| **CC** | Controlled Correspondence |
| **CDER** | Center for Drug Evaluation and Research |
| **CGMP** | Current Good Manufacturing Practice |
| **CPA** | Capacity Planning Adjustment |
| **CQA** | Critical Quality Attributes |
| **CR** | Complete Response |
| **CRL** | Complete Response Letter |
| **DDCP** | Drug-Device Combination Products |
| **DMF** | Drug Master File |
| **DRL** | Discipline Review Letter |
| **eCTD** | Electronic Common Technical Document |
| **EMCRM** | Enhanced Mid-Cycle Review Meeting |
| **ETASU** | Elements to Assure Safe Use |
| **EU** | European Union |
| **FDA** | Food and Drug Administration |
| **FD&C Act** | Federal Food, Drug, and Cosmetic Act |
| **FDF** | Finished Dosage Form |
| **FTE** | Full-Time Equivalent |
| **FY** | Fiscal Year (October 1 to September 30) |
| **GDUFA** | Generic Drug User Fee Amendments |
| **GDUFA I** | Generic Drug User Fee Amendments of 2012 |
| **GDUFA II** | Generic Drug User Fee Amendments of 2017 |
| **GDUFA III** | Generic Drug User Fee Amendments of 2022 |
| **IA** | Import Alert |
| **ICH** | The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| **IR** | Information Request |
| **LAI** | Long-Acting Injectable |
| **MAPP** | Manual of Policies and Procedures |
| **MIE** | Model-Integrated Evidence |
| **ML** | Machine Learning |

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

# I. Introduction

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

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

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

[1] According to a report compiled by the Association for Accessible Medicines that was primarily based on data from IQVIA, the American healthcare system saved nearly $3.4 trillion in the last 10 years due to the availability of affordable generics. The report is available at https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf .

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

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

## A. Performance Presented in This Report

GDUFA commitments cover a wide range of improvements, including enhancing communications between FDA and industry throughout the review process, enhancing communications from FDA regarding inspections of facilities and sites, improving predictability and transparency, promoting the efficiency and effectiveness of the review process, enhancing drug master file (DMF) reviews, enhancing accountability and reporting, and advancing regulatory science initiatives. This report details FDA's updated performance results for the second year of GDUFA III (i.e., FY 2023 and FY 2024) and preliminary performance results for the third year of GDUFA III (i.e., FY 2025). This report also presents the Agency's progress in accomplishing the program goals and enhancements of GDUFA III. Unless otherwise noted, updated data for FYs 2023 and 2024 and preliminary data for FY 2025 are as of September 30, 2025.

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

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

- For a commitment letter goal pertaining to review timeframes to be met, FDA needs to review the specified percentage of submissions within that goal's timeframe. For example, in FY 2025, to meet the goal for standard original ANDAs, FDA would review and act on 90 percent of them within 10 months.

- Consistent with section XI.A of the GDUFA III Commitment letter, to "act on" an ANDA means that FDA will issue a complete response letter (CRL), an approval letter, a tentative approval (TA) letter, or a refuse-to-receive (RTR) letter.

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

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

# II. GDUFA Performance Goals

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

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

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

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

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

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

Tables 2, 3 and 4 represent FDA's FY 2023 updated performance data, FY 2024 updated performance data and FY 2025 preliminary performance data, respectively. The "Percent on Time" column shows the percentage of submissions reviewed on time as of September 30, 2025, excluding action pending within the GDUFA review goal, and the "Potential Range" column shows the potential for meeting the FY 2025 GDUFA review goal.

The 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 tentative approval 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 tentative approval within 60 days of the goal date rather than to act on the goal date, e.g., issue a CRL. Under the GDUFA III Commitment Letter, if an ANDA is approved or tentatively approved within 60 days after the goal date, the goal date will be considered to have been met. FDA will

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

## A. FY 2023 Updated Performance Data

Table 2 contains the updated performance data for the FY 2023 performance goals that were reported as open in last year's performance report. The table shows that FDA met or exceeded the updated goals for that cohort.

**Table 2. GDUFA III FY 2023 Updated Performance Goal Results**

| GDUFA III FY 2023 Updated Performance Goals by Submission Type | Review Time Goal | Actions Complete* | Percent on Time† | Potential Range‡ | On Time Imminent Action§ | Imminent Action Potential Range |
|---|---|---|---|---|---|---|
| **Original ANDA Goals** | | | | | | |
| Standard Original ANDA Submissions | 10/30¶ months | 569 of 569 | 92% | 92% to 92% | 94% | 94% to 94% |
| Priority Original ANDA Submissions | 8/10/30 months | 155 of 155 | 88% | 88% to 88% | 93% | 93% to 93% |

## B. FY 2024 Updated Performance Data

Table 3 contains the updated performance data for the FY 2024 cohort, which shows that FDA met or exceeded a majority of the goals for that cohort.

**Table 3. GDUFA III FY 2024 Updated Performance Goal Results**

| GDUFA III FY 2024 Updated Performance Goals by Submission Type | Review Time Goal | Actions Complete* | Percent on Time† | Potential Range‡ | On Time Imminent Action§ | Imminent Action Potential Range |
|---|---|---|---|---|---|---|
| **Original ANDA Goals** | | | | | | |
| Standard Original ANDA Submissions | 10/30¶ months | 500 of 559 | 93% | 84% to 94% | 97% | 87% to 97% |
| Priority Original ANDA Submissions | 8/10/30 months | 160 of 174 | 96% | 89% to 96% | 98% | 90% to 98% |
| **Amendment Goals** | | | | | | |
| Standard Major ANDA Amendments | 8/10 months | 573 of 587 | 94% | 91% to 94% | 96% | 94% to 96% |
| Priority Major ANDA Amendments | 6/8/10 months | 111 of 111 | 86% | 86% to 86% | 86% | 86% to 86% |
| Standard and Priority Minor ANDA Amendments | 3 months | 812 of 817 | 85% | 85% to 85% | 96% | 95% to 96% |
| Unsolicited ANDA Amendments | Varies | 529 of 545 | 85% | 83% to 85% | -- | -- |

| GDUFA III FY 2024 Updated Performance Goals by Submission Type | Review Time Goal | Actions Complete* | Percent on Time† | Potential Range‡ | On Time Imminent Action§ | Imminent Action Potential Range |
|---|---|---|---|---|---|---|
| **PAS Goals** | | | | | | |
| Standard PAS | 6/10 months | 1639 of 1639 | 98% | 98% to 98% | 99% | 99% to 99% |
| Priority PAS | 4/8/10 months | 91 of 91 | 98% | 98% to 98% | 99% | 99% to 99% |
| **PAS Amendment Goals** | | | | | | |
| Standard Major PAS Amendment | 6/10 months | 90 of 90 | 97% | 97% to 97% | 97% | 97% to 97% |
| Priority Major PAS Amendment | 4/8/10 months | 13 of 13 | 100% | 100% to 100% | 100% | 100% to 100% |
| Standard and Priority Minor PAS Amendments | 3 months | 239 of 240 | 96% | 96% to 96% | 97% | 97% to 97% |
| Unsolicited PAS Amendments | Varies | 21 of 21 | 90% | 90% to 90% | -- | -- |
| **DMF Goals** | | | | | | |
| Complete the Initial Completeness Assessment Review of Type II API DMFs | 60 calendar days | 358 of 358 | 99% | 99% to 99% | -- | -- |
| **CC Goals** | | | | | | |
| Level I CC | 60 calendar days | 2974 of 2974 | 99% | 99% to 99% | -- | -- |
| Level II CC | 120 calendar days | 456 of 456 | 98% | 98% to 98% | -- | -- |
| Clarification of Ambiguities in CC Response | 21 calendar days | 16 of 16 | 94% | 94% to 94% | -- | -- |

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

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

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

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

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

## C. FY 2025 Preliminary Performance Data

Table 4 contains the preliminary performance data for the FY 2025 cohort.

## Table 4. GDUFA III FY 2025 Preliminary Performance Goal Results

| GDUFA III FY 2025 Preliminary Performance Goals by Submission Type | Review Time Goal | Actions Complete* | Percent on Time† | Potential Range‡ | On Time Imminent Action§ | Imminent Action Potential Range |
|---|---|---|---|---|---|---|
| **Original ANDA Goals** | | | | | | |
| Standard Original ANDA Submissions | 10/30¶ months | 29 of 400 | 97% | 7% to 99% | 100% | 7% to 100% |
| Priority Original ANDA Submissions | 8/10/30 months | 10 of 84 | 100% | 12% to 100% | 100% | 12% to 100% |
| **Amendment Goals** | | | | | | |
| Standard Major ANDA Amendments | 8/10 months | 169 of 521 | 95% | 31% to 98% | 98% | 32% to 99% |
| Priority Major ANDA Amendments | 6/8/10 months | 41 of 88 | 100% | 47% to 100% | 100% | 47% to 100% |
| Standard and Priority Minor ANDA Amendments | 3 months | 485 of 746 | 86% | 58% to 91% | 98% | 64% to 98% |
| Unsolicited ANDA Amendments | Varies | 238 of 416 | 82% | 49% to 89% | -- | -- |
| **PAS Goals** | | | | | | |
| Standard PAS | 6/10 months | 980 of 1712 | 99% | 57% to 99% | 99% | 57% to 99% |
| Priority PAS | 4/8/10 months | 90 of 122 | 96% | 72% to 97% | 99% | 73% to 99% |
| **PAS Amendment Goals** | | | | | | |
| Standard Major PAS Amendment | 6/10 months | 51 of 103 | 100% | 50% to 100% | 100% | 50% to 100% |
| Priority Major PAS Amendment | 4/8/10 months | 8 of 11 | 88% | 64% to 91% | 100% | 73% to 100% |
| Standard and Priority Minor PAS Amendments | 3 months | 200 of 247 | 98% | 79% to 98% | 99% | 81% To 99% |
| Unsolicited PAS Amendments | Varies | 21 of 28 | 100% | 75% to 100% | -- | -- |
| **DMF Goals** | | | | | | |
| Complete the Initial Completeness Assessment Review of Type II API DMFs | Within 60 calendar days of the later of the date of DMF submission or DMF Fee payment | 322 of 322 | 99% | 99% to 99% | -- | -- |
| **CC Goals** | | | | | | |
| Level I CC | Within 60 calendar days of submission date | 3021 of 3323 | 100% | 91% to 100% | -- | -- |

| GDUFA III FY 2025 Preliminary Performance Goals by Submission Type | Review Time Goal | Actions Complete* | Percent on Time† | Potential Range‡ | On Time Imminent Action§ | Imminent Action Potential Range |
|---|---|---|---|---|---|---|
| Level II CC | Within 120 calendar days of submission date | 463 of 608 | 99% | 76% to 99% | -- | -- |
| Clarification of Ambiguities in CC Response | Within 21 calendar days of request receipt | 18 of 18 | 100% | 100% to 100% | -- | -- |

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

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

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

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

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

# III. GDUFA Program Enhancement and Other Goals

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

Under GDUFA III, FDA continues to leverage program enhancement goals to improve its predictability and transparency, promote the efficiency and effectiveness of the assessment process, minimize the number of assessment cycles necessary for approval, increase the overall rate of approval, and facilitate greater access to generic drug products. Table 5 reflects the program enhancement goals for FYs 2023 to 2027 described in sections II to VII of the GDUFA III Commitment Letter.

**Table 5. 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 |
|---|---|---|---|---|---|---|
| **Assessment Classification Changes During Assessment Cycle** | | | | | | |
| FDA to notify the applicant if the assessment classification of the ANDA or PAS changes from standard to priority during an assessment cycle of an ANDA or PAS | Within 14 calendar days of the date of the change | -- | -- | -- | -- | -- |
| FDA to decide whether to reclassify a major amendment or standard assessment status | Within 30 calendar days of date of FDA's receipt of the request for a teleconference | 90% | 90% | 90% | 90% | 90% |
| FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Priority Amendments | Within 30 calendar days of date of FDA's receipt of the request for a reclassification | -- | -- | -- | -- | -- |
| FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Standard Amendments | Within 60 calendar days of date of FDA's receipt of the request for a reclassification | -- | -- | -- | -- | -- |
| **Dispute Resolution** | | | | | | |
| FDA to respond to appeals above the Division level | Within 30 calendar days of FDA's receipt of the written | 90% | 90% | 90% | 90% | 90% |

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

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

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

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

## A. FY 2024 Updated Program Enhancement and Other Goal Results

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

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

| GDUFA III FY 2024 Updated Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| **Assessment Classification Changes During Assessment Cycle** | | | | | |
| FDA to notify the applicant if the assessment classification of the ANDA or PAS changes from standard to priority during an assessment cycle of an ANDA or PAS | Within 14 calendar days of the date of the change | -- | 25 of 25 | 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% | 92 of 92 | 99% | 99% to 99% |

| GDUFA III FY 2024 Updated Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Priority Amendments | Within 30 calendar days of date of FDA's receipt of the request for a reclassification | -- | 21 of 21 | 100% | 100% to 100% |
| FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Standard Amendments | Within 60 calendar days of date of FDA's receipt of the request for a reclassification | -- | 130 of 130 | 100% | 100% to 100% |
| **Dispute Resolution** | | | | | |
| FDA to respond to appeals above the Division level | Within 30 calendar days of FDA's receipt of the written appeal pursuant to the applicable goal | 90% | 5 of 5 | 100% | 100% to 100% |
| **Suitability Petitions** | | | | | |
| FDA to review and respond to suitability petitions that have been assigned a goal date | Within 6 months after completeness assessment, up to the maximum number of suitability petitions completed as described in Section III.B. of the GDUFA III Commitment Letter | 50% | 103 of 103 | 96% | 96% to 96% |
| **PSGs for Complex and Non-Complex Drug Products** | | | | | |
| Complex products approved in NDAs | Within 2 years of approval | 50% | -- | -- | -- |
| Complex products approved in NDAs | Within 3 years of approval | 75% | -- | -- | -- |
| Non-complex products approved in NDAs that contain an NCE | Within 2 years of approval | 90% | 19 of 19 | 100% | 100% to 100% |
| **PSG Teleconference and Meetings** | | | | | |
| FDA to conduct a PSG Teleconference granted | Within 30 calendar days from receipt of request | -- | 1 of 1 | 100% | 100% to 100% |
| FDA to grant or deny a meeting request for a Pre-Submission PSG Meeting if the applicant has not submitted an ANDA | Within 14 calendar days from receipt of request | -- | -- | -- | -- |

| GDUFA III FY 2024 Updated Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| FDA to schedule Pre-Submission PSG Meeting granted if the applicant has not submitted an ANDA | Within 120 calendar days of receipt of request | -- | -- | -- | -- |
| FDA to grant or deny a meeting request for a Post-Submission PSG Meeting if the applicant has submitted an ANDA | Within 14 calendar days from receipt of request | -- | -- | -- | -- |
| FDA to schedule Post-Submission PSG Meeting granted if the applicant has submitted an ANDA | Within 90 calendar days of receipt of request | -- | -- | -- | -- |
| **Product Development Meetings** | | | | | |
| FDA to grant or deny Product Development Meeting Requests | Within 14 calendar days from receipt of request | 90% | 85 of 85 | 99% | 99% to 99% |
| FDA to conduct or provide written response to Product Development Meetings granted | Within 120 calendar days after the meeting is granted | 90% | 69 of 69 | 100% | 100% to 100% |
| Unless FDA is providing a written response to satisfy the meeting goal, FDA to aspire to provide preliminary written comments before each Product Development Meeting | 5 calendar days before the meeting | -- | 42 of 42 | 100% | 100% to 100% |
| FDA to provide meeting minutes | Within 30 calendar days following the meeting | -- | 28 of 28 | 100% | 100% to 100% |
| **Pre-Submission Meetings** | | | | | |
| FDA to grant or deny Pre-Submission Meeting Requests | Within 30 calendar days from receipt of request | 90% | 3 of 3 | 100% | 100% to 100% |
| FDA to conduct Pre-Submission Meetings granted | Within 60 calendar days from receipt of request | 90% | -- | -- | -- |
| If appropriate to the purpose of the meeting, FDA to provide preliminary written comments | 5 calendar days before each meeting | -- | -- | -- | -- |
| FDA to provide meeting minutes | Within 30 calendar days of the meeting | -- | -- | -- | -- |
| **Mid-Cycle Review Meeting (MCRM)** | | | | | |

| GDUFA III FY 2024 Updated Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| FDA to conduct a MCRM granted | Within 30 calendar days after the date the sponsor submits a meeting request | -- | 6 of 6 | 100% | 100% to 100% |
| **Enhanced Mid Cycle Review Meeting (EMCRM)** | | | | | |
| FDA to conduct a EMCRM granted | Within 90 calendar days after issuance of the last mid-cycle DRL | -- | 4 of 4 | 100% | 100% to 100% |
| **Post-CRL Teleconference Meetings** | | | | | |
| FDA to provide a scheduled date for a requested Post-CRL teleconference | Within 14 calendar days of the request for a teleconference | 90% | 72 of 72 | 89% | 89% to 89% |
| FDA to conduct requested Post-CRL teleconferences on the FDA-proposed date | Within 30 calendar days of the receipt of the written request | 90% | 72 of 72 | 99% | 99% to 99% |
| **Post-CRL Scientific Meetings** | | | | | |
| FDA to grant or deny Post-CRL scientific meeting requests | Within 14 calendar days from receipt of the request | -- | 14 of 14 | 93% | 93% to 93% |
| FDA to conduct or provide written response to Post-CRL scientific meeting granted | Within 90 calendar days of granting request | -- | 10 of 10 | 100% | 100% to 100% |
| **DMF First Cycle Review Deficiency** | | | | | |
| FDA to strive to grant DMF first cycle review deficiency teleconferences | Within 30 calendar days from receipt of request | -- | 1 of 1 | 100% | 100% to 100% |
| **Foreign Regulators** | | | | | |
| FDA to issue written communication conveying the current compliance status for establishment physically located in the United States that has been included as part of a marketing application submitted to a foreign regulator | Within 30 calendar days of date of receipt of request | -- | 25 of 25 | 100% | 100% to 100% |
| **Post-WL Meetings** | | | | | |
| FDA to grant, deny, or defer in favor of re-inspection a Post-WL Meeting | Within 30 calendar days from receipt of request | 50% | 5 of 5 | 80% | 80% - 80% |

| GDUFA III FY 2024 Updated Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| **Re-Inspection** | | | | | |
| FDA agrees to notify the facility of the Agency's decision to re-inspect | Within 30 calendar days from receipt of request | -- | -- | -- | -- |
| If re-inspection is granted, FDA to re-inspect the facility: | | | | | |
| Domestic | Within 4 months of the letter to the facility indicating FDA's intent to reinspect | 60% | -- | -- | -- |
| International | Within 8 months of the letter to the facility indicating FDA's intent to reinspect | 60% | -- | -- | -- |

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

## B. FY 2025 Preliminary Program Enhancement and Other Goal Results

Table 7 represents FDA's FY 2025 preliminary program enhancement goal results.

### Table 7. GDUFA III FY 2025 Preliminary Program Enhancement and Other Goal Results

| GDUFA III FY 2025 Preliminary Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| **Assessment Classification Changes During Assessment Cycle** | | | | | |
| FDA to notify the applicant if the assessment classification of the ANDA or PAS changes from standard to priority during an assessment cycle of an ANDA or PAS | Within 14 calendar days of the date of the change | -- | 30 of 30 | 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% | 72 of 74 | 99% | 96% to 99% |
| FDA to decide on a request for reclassification of a Facility- | Within 30 calendar days of date of FDA's receipt of | -- | 10 of 11 | 100% | 91% to 100% |

| GDUFA III FY 2025 Preliminary Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| Based Major CRL Amendment for Priority Amendments | the request for a reclassification | | | | |
| FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Standard Amendments | Within 60 calendar days of date of FDA's receipt of the request for a reclassification | -- | 61 of 70 | 100% | 87% to 100% |
| **Dispute Resolution** | | | | | |
| FDA to respond to appeals above the Division level | Within 30 calendar days of FDA's receipt of the written appeal pursuant to the applicable goal | 90% | 6 of 7 | 100% | 86% to 100% |
| **Suitability Petitions** | | | | | |
| FDA to review and respond to suitability petitions that have been assigned a goal date | Within 6 months after completeness assessment, up to a maximum of 70 suitability petitions completed | 70% | 55 of 94 | 100% | 59% to 100% |
| **PSGs for Complex and Non-Complex Drug Products** | | | | | |
| Complex products approved in NDAs | Within 2 years of approval | 50% | 16 of 20 | 100% | 80% to 100% |
| Complex products approved in NDAs | Within 3 years of approval | 75% | | | |
| Non-complex products approved in NDAs that contain an NCE | Within 2 years of approval | 90% | 28 of 28 | 100% | 100% to 100% |
| **PSG Teleconference and Meetings** | | | | | |
| FDA to conduct a PSG Teleconference granted | Within 30 calendar days from receipt of request | -- | 3 of 3 | 100% | 100% to 100% |
| FDA to grant or deny a meeting request for a Pre-Submission PSG Meeting if the applicant has not submitted an ANDA | Within 14 calendar days from receipt of request | -- | | | |
| FDA to schedule Pre-Submission PSG Meeting granted if the applicant has not submitted an ANDA | Within 120 calendar days of receipt | -- | | | |
| FDA to grant or deny a meeting request for a Post-Submission PSG Meeting if the applicant has submitted an ANDA | Within 14 calendar days from receipt of request | -- | | | |
| FDA to schedule Post-Submission PSG Meeting granted if the applicant has submitted an ANDA | Within 90 calendar days of receipt of request | -- | | | |
| **Product Development Meetings** | | | | | |

| GDUFA III FY 2025 Preliminary Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| FDA to grant or deny Product Development Meeting Requests | Within 14 calendar days from receipt of request | 90% | 92 of 97 | 100% | 95% to 100% |
| FDA to conduct or provide written response to Product Development Meetings granted | Within 120 calendar days after the meeting is granted | 90% | 73 of 80 | 100% | 91% 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 | -- | 37 of 47 | 100% | 79% to 100% |
| FDA to provide meeting minutes | Within 30 calendar days following the meeting | -- | 14 of 21 | 100% | 67% to 100% |
| **Pre-Submission Meetings** | | | | | |
| FDA to grant or deny Pre-Submission Meeting Requests | Within 30 calendar days from receipt of request | 90% | 7 of 7 | 100% | 100% to 100% |
| FDA to conduct Pre-Submission Meetings granted | Within 60 calendar days of receipt of request | 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% |
| **Mid-Cycle Review Meeting (MCRM)** | | | | | |
| FDA to conduct an MCRM granted | Within 30 calendar days after the date the sponsor submits a meeting request | -- | 6 of 6 | 100% | 100% to 100% |
| **Enhanced Mid Cycle Review Meeting (EMCRM)** | | | | | |
| FDA to conduct an EMCRM granted | Within 90 calendar days after issuance of the last mid-cycle DRL | -- | 6 of 7 | 100% | 86% to 100% |
| **Post-CRL Teleconference Meetings** | | | | | |
| FDA to provide a scheduled date for a requested Post-CRL teleconference | Within 14 calendar days of the request for a teleconference | 90% | 65 of 68 | 94% | 90% to 94% |
| FDA to conduct requested Post-CRL teleconferences on the FDA-proposed date | Within 30 calendar days of the receipt of the written request | 90% | 65 of 68 | 97% | 93% to 97% |
| **Post-CRL Scientific Meetings** | | | | | |

| GDUFA III FY 2025 Preliminary Performance | Review Goal | Goal | Actions* Completed | Percent on† Time | Potential‡ Range |
|---|---|---|---|---|---|
| FDA to grant or deny Post-CRL scientific meeting requests | Within 14 calendar days of the request for a teleconference | -- | 18 of 19 | 100% | 95% to 100% |
| FDA to conduct or provide written response to Post-CRL scientific meeting granted | Within 90 calendar days of the receipt of the written request | -- | 11 of 14 | 91% | 71% to 91% |
| **DMF First Cycle Review Deficiency** | | | | | |
| FDA to strive to grant DMF first cycle review deficiency teleconferences | Within 30 calendar days from receipt of request | -- | 5 of 5 | 100% | 100% to 100% |
| **Foreign Regulators** | | | | | |
| FDA to issue written communication conveying the current compliance status for establishment physically located in the United States that has been included as part of a marketing application submitted to that foreign regulator | Within 30 calendar days of date of receipt of request | -- | 108 of 108 | 100% | 100% to 100% |
| **Post-WL Meetings** | | | | | |
| FDA to grant, deny, or defer in favor of re-inspection a Post-WL Meeting | Within 30 calendar days from receipt of request | 70% | 4 of 5 | 100% | 80% to 100% |
| **Re-Inspection** | | | | | |
| FDA agrees to notify the facility of the Agency's decision to re-inspect | Within 30 calendar days from receipt of request | -- | 4 of 4 | 100% | 100% to 100% |
| 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 | 70% | N/A | -- | -- |
| International | Within 8 months of the letter to the facility indicating FDA's intent to reinspect | 70% | N/A | -- | -- |

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

# IV. Additional Activities to Implement GDUFA Commitments

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

## A. Policy Document Highlights

In FY 2025, FDA published many guidances for industry[4] 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 2025, FDA published the following guidances for industry:

- Final guidance for industry: M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms (October 2024).
- Final guidance for industry: Requests for Reconsideration at the Division Level Under GDUFA (October 2024).
- Final guidance for industry: Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA (October 2024).
- Draft guidance for industry: M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver (May 2025).
- Final guidance for industry: Post-Warning Letter Meetings Under GDUFA (June 2025).
- Final guidance for industry: ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions (June 2025).

These guidances 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.

These guidances are intended to provide industry with comprehensive recommendations to help streamline the generic drug development process without compromising the rigorous standards for product quality and manufacturing required under the FD&C Act. The pre-submission facility correspondence and DMF early assessment guidances are designed to facilitate proactive engagement with FDA, helping applicants to address potential facility and manufacturing issues before formal

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

ANDA submission, thereby reducing the likelihood of assessment delays and facilitating priority review designations, as eligible. The post-warning letter meeting guidance describes a structured pathway for facilities to engage with FDA on remediation efforts, promoting more efficient resolution of compliance issues. Meanwhile, the requests for reconsideration guidance clarifies dispute resolution procedures, helping ensure applicants have clear avenues to address disagreements with FDA decisions. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) M13A and M13B guidances provide detailed scientific recommendations that can help facilitate harmonization across jurisdictions while assisting applicants in providing a robust demonstration of therapeutic equivalence. Collectively, these guidances help operationalize the GDUFA III commitment letter's vision of maximizing assessment efficiency, reducing review cycles, and ultimately facilitating timely patient access to safe, effective, and affordable generic medicines.

## B. Suitability Petition Highlights

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

Under the GDUFA III Commitment Letter, FDA agreed to conduct a completeness assessment for suitability petitions submitted in FYs 2024 to 2027. Table 8 reflects the timeframe for suitability petition completeness assessments.

**Table 8. GDUFA III Timeframe for Suitability Petition Completeness Assessments**

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

Beginning in FY 2024, FDA committed to reviewing and responding to suitability petitions that have been assigned a goal date. Table 9 reflects the suitability petition goals as described in section III of the GDUFA III Commitment Letter.

### Table 9. GDUFA III Suitability Petition Goals

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

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

In FY 2025, 94 suitability petitions were submitted to FDA and assigned goal dates.

Table 10 provides information on the suitability petition completeness assessments conducted in FY 2025.

### Table 10. FY 2025 Suitability Petition Completeness Assessments

| GDUFA III Suitability Petition | Timeline | Actions Completed | Percent on Time |
|---|---|---|---|
| Conduct completeness assessment for suitability petitions | 21 days after the date of petition submission | 72 | 100% |
| If an IR is issued as part of the completeness assessment and the petitioner submits a response | 21 days after the date of receipt of the IR response | 22 | 100% |

In FY 2025, FDA completed 55 suitability petitions. Table 11 reports the percentage of suitability petitions completed within 6 months after FDA had completed the completeness assessment.

### Table 11. FY 2025 Suitability Petition Goal Results

| GDUFA III FY 2025 Preliminary Suitability Petition Goal Results | Review Goal | Goal | Actions Completed | Percent on Time | Potential Range |
|---|---|---|---|---|---|
| Review and respond to suitability petitions that have been assigned a goal date | 6 months after completeness assessment up to a maximum of 70 suitability petitions completed | 70% | 55 | 100% | 59% to 100% |

## C. GDUFA Regulatory Science and Research Highlights

### *1. Outreach Highlights*

In FY 2025, as shown in Table 12, FDA hosted or co-hosted 12 meetings, webinars, and public workshops to promote transparency through regulatory and scientific outreach and to facilitate enhanced communications through dialogue with academic experts and pharmaceutical industry representatives on numerous issues impacting generic drugs.

**Table 12. FDA's GDUFA-Related Meetings, Webinars, and Public Workshops in FY 2025**

| GDUFA-Related Meetings, Webinars, and Public Workshops | Date Held |
|---|---|
| **FDA and Center for Research on Complex Generics Co-Hosted Workshop on Scientific and Regulatory Considerations for Assessment of Immunogenicity Risk for Generic Peptide and Oligonucleotide Drug Products**[5]<br><br>This two-day workshop engaged stakeholders from industry, academia, and FDA in discussions on scientific and regulatory challenges associated with immunogenicity risk assessment for proposed generic peptide and oligonucleotide drug products. Discussions focused on best practices for assessing immunogenicity risk from product- and process-related impurities in synthetic generic peptide products, including the use of in silico and in vitro assays to assess MHC binding and T cell responses. Immunogenicity risk assessment strategies for recombinant peptide and generic oligonucleotide products were a key focus of the workshop, with presentations from regulatory, academic, and industrial experts providing clarity on useful strategies, potential pitfalls, and regulatory expectations. | 10/7/2024 – 10/8/2024 |
| **FDA and Center for Research on Complex Generics Co-Hosted Workshop on Updates on Approaches to Acceptable Intakes of Nitrosamine Drug Substance Related Impurities (NDSRIs) and Bioequivalence Assessment for Reformulated Drug Products**[6]<br><br>This two-day workshop facilitated discussions on confirmatory test methods for NDSRI formation, safety testing methods for NDSRIs, and recommended acceptable intake limits. Presentations during the workshop shared the latest research and recommendations for detecting NDSRI formation, strategies to mitigate the risk of forming NDSRIs, and regulatory approaches for pre- and post-approval changes in ANDA submissions and supplements. Discussions during the workshop addressed formulation stability and bioequivalence approaches for reformulated drug products to ensure compliance with regulatory requirements. | 11/6/2024 – 11/7/2024 |
| **FDA SBIA Webinar on M13A: Bioequivalence for Immediate-Release Solid Oral Dosage Forms - Implementing the Final Guidance**[7] | 11/21/2024 |

[5] https://www.fda.gov/drugs/news-events-human-drugs/scientific-and-regulatory-considerations-assessment-immunogenicity-risk-generic-peptide-and

[6] https://www.fda.gov/drugs/news-events-human-drugs/updates-approaches-acceptable-intakes-nitrosamine-drug-substance-related-impurities-and

[7] https://www.fda.gov/drugs/news-events-human-drugs/m13a-bioequivalence-immediate-release-solid-oral-dosage-forms-implementing-final-guidance-11212024

| GDUFA-Related Meetings, Webinars, and Public Workshops | Date Held |
|---|---|
| This webinar provided an update and overview of the final International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms guideline, including major changes from the draft guideline and FDA's current draft bioequivalence guidance. FDA outlined its implementation planning for M13A and addressed questions and clarifications based on comments received during public consultation of the draft guideline. Discussions during the webinar provided information relating to conducting bioequivalence studies for orally administered immediate-release solid oral dosage forms designed to deliver drugs to the systemic circulation. | |
| **FDA and Center for Research on Complex Generics Co-Hosted Workshop on Navigating the Transition to Low Global Warming Potential Propellants**[8]<br><br>This two-day workshop engaged subject matter experts from academia, brand name and generic drug companies, and regulatory agencies to discuss the scientific understanding of low global warming potential (LGWP) propellants, focusing on challenges for transitioning generic metered dose inhalers (MDIs) to use LGWP propellants. Discussions encompassed the development of brand name MDI products with LGWP propellants, and covered lessons learned from previous propellant transitions. A key topic was how transitions to LGWP propellants may impact product performance and bioequivalence. | 12/4/2024 – 12/5/2024 |
| **FDA SBIA Webinar on Navigating Controlled Correspondences to Support Generic Drug Development**[9]<br><br>This webinar provided a comprehensive overview of controlled correspondences (CCs) as an efficient pathway for communication with FDA regarding generic drug development. The event included detailed discussions about CCs related to formulation assessments and bioequivalence approaches. Other topics discussed included clinical pharmacology issues and safety evaluations for generic drugs. | 2/27/2025 |
| **FDA SBIA Webinar on Model Master Files: Advancing Modeling and Simulation in Generic Drug Development and Regulatory Submissions**[10]<br><br>This webinar provided an update on FDA's efforts related to model master files (MMFs), including an introduction and overview of MMFs, considerations for developing and submitting MMFs to support ANDAs using a Type V DMF, and cross-comparisons to other types of DMFs. The presentations focused on the purpose, benefits, and challenges associated with MMFs, how to navigate a Type V DMF process for MMF submissions, and best practices when submitting an MMF. | 3/13/2025 |
| **FDA Generic Drugs Forum (GDF) 2025**[11]<br><br>This two-day forum focused on facilitating the development and approval of safe, effective, and high-quality generic drugs by bringing together FDA subject matter experts to discuss myriad aspects of the pre-ANDA and ANDA assessment process. The forum provided practical regulatory knowledge to enhance applications, help streamline the assessment process, and reduce the number of review cycles. The primary goal was to support prospective and current applicants in submitting complete and high-quality submissions that are consistent with FDA's expectations and regulatory requirements, to help ensure timely patient access to affordable medications that benefit public health. | 4/9/2025 – 4/10/2025 |

[8] https://www.fda.gov/drugs/news-events-human-drugs/navigating-transition-low-global-warming-potential-propellants-12042024

[9] https://www.fda.gov/drugs/news-events-human-drugs/navigating-controlled-correspondences-support-generic-drug-development-02272025

[10] https://www.fda.gov/drugs/news-events-human-drugs/model-master-files-advancing-modeling-and-simulation-generic-drug-development-and-regulatory

[11] https://www.fda.gov/drugs/news-events-human-drugs/generic-drugs-forum-gdf-2025-04092025

| GDUFA-Related Meetings, Webinars, and Public Workshops | Date Held |
|---|---|
| **FDA and Center for Research on Complex Generics Co-Hosted Workshop on Implementing FDA's IVPT Guidance Recommendations: A Step-By-Step Illustration**[12]<br><br>This two-day workshop clarified how to implement the FDA's recommendations for In Vitro Permeation Test (IVPT) studies, with step-by-step demonstrations illustrating how IVPT study procedures can be performed in a manner that is compatible with recommendations made in FDA's Guidance for Industry on IVPT Studies for Topical Drug Products Submitted in ANDAs. The workshop focused on IVPT method development and validation procedures that ANDA applicants often find challenging to implement, demonstrating procedures using different IVPT diffusion cell systems from major manufacturers. | 4/29/2025 – 4/30/2025 |
| **FDA Public Workshop on Fiscal Year 2025 Generic Drug Science and Research Initiatives**[13]<br><br>This two-day workshop provided an overview of the status of science and research initiatives for generic drugs and provided an opportunity for public input on these initiatives. Specifically, FDA sought input from the generic drug industry, academia, patient advocates, professional societies, and other interested parties to fulfill its GDUFA III commitment and develop an annual list of science and research initiatives for FY 2026. Presentations and discussions focused on identifying what research is needed to address scientific knowledge gaps that are impacting generic product development and regulatory assessment, including challenges for generic drug developers related to complex active pharmaceutical ingredients, complex products, and oral products. | 6/3/2025 – 6/4/2025 |
| **FDA Public Meeting on the Reauthorization of the Generic Drug User Fee Amendments (GDUFA)**[14]<br><br>This public meeting discussed proposed recommendations for the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for fiscal years 2028 through 2032 (i.e., GDUFA IV). The meeting provided a forum for stakeholder input on the future direction of the GDUFA program and its impact on generic drug development and facilitation of efficient review processes. | 7/11/2025 |
| **FDA Webinar on ICH M13B: Navigating the Draft ICH M13B Additional Strengths Biowaiver Guideline**[15]<br><br>This webinar provided an in-depth look at the draft ICH M13B guideline on Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver (which addresses waivers of bioequivalence studies for additional strengths when in vivo bioequivalence has been demonstrated for at least one strength). During the webinar, FDA experts explained the rationale behind the ICH M13 Expert Working Group's proposed recommendations in the draft guideline, highlighted areas where ICH recommendations differed from FDA's current recommendation on additional strength biowaiver, and provided clarification on the draft guideline. The webinar sought to stimulate public comments on the draft guideline. | 9/11/2025 |

[12] https://www.fda.gov/drugs/news-events-human-drugs/implementing-fdas-ivpt-guidance-recommendations-step-step-illustration-04292025

[13] https://www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2025-generic-drug-science-and-research-initiatives-public-workshop-06032025

[14] https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-generic-drug-user-fee-amendments-gdufa-07112025

[15] https://www.fda.gov/drugs/news-events-human-drugs/ich-m13b-webinar-navigating-draft-ich-m13b-additional-strengths-biowaiver-guideline-09112025

| GDUFA-Related Meetings, Webinars, and Public Workshops | Date Held |
|---|---|
| FDA and Center for Research on Complex Generics Co-Hosted Workshop on Mastering Particle Size Analysis: A Step-By-Step Illustration of Techniques and Best Practices[16]<br><br>This two-day workshop provided theoretical and practical insights about performing particle size measurements with a diverse and challenging range of products, including emulsions and suspensions. The workshop included hands-on, step-by-step procedures demonstrating techniques for particle size distribution measurement that are crucial for quality control and bioequivalence demonstrations with complex generic drug products. Discussions focused on common particle sizing techniques such as dynamic light scattering and laser diffraction, common deficiencies encountered during quality assessments, and best practices for method development, validation, and reporting. | 9/23/2025 – 9/24/2025 |

## D. Contract and Grant Highlights

Research outcomes serve as the scientific basis for the development of PSGs and specific pre-ANDA communications. Since FY 2013, FDA has awarded 236 research contracts and grants. A complete list of FY 2013 through FY 2025 awards can be found at https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects. The number of new and ongoing grants and contracts in GDUFA III by fiscal year is provided in Table 13.

### Table 13. GDUFA III New and Ongoing Grants and Contracts by Fiscal Year

| Fiscal Year | Number of External Research Contracts and Grants Awarded Using GDUFA Funds | |
|---|---|---|
| | New Contracts and Grants | Ongoing Contracts and Grants Receiving Funding |
| 2023 | 20 | 25 |
| 2024 | 13 | 27 |
| 2025 | 0 | 25 |

## E. FY 2025 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.

[16] https://www.fda.gov/drugs/news-events-human-drugs/fdacenter-research-complex-generics-crcg-workshop-mastering-particle-size-analysis-step-step

The FY 2025 GDUFA Science and Research Program included the following eight research areas that correspond to the eight GDUFA Science and Research Priority Initiatives for FY 2025.[17]

1. Develop Methods for Generics to Address Impurities Such as Nitrosamines.

2. Enhance the Efficiency of Equivalence 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 Equivalence Approaches for Complex Drug-Device Combination Products.

6. Improve the Efficiency of BE Approaches for Oral and Parenteral Generic Products.

7. Facilitate the Utility of Model-Integrated Evidence (MIE) to Support Demonstrations of BE.

8. Expand the Use of Artificial Intelligence (AI) and Machine Learning (ML) Tools.

A synopsis of the research activities and accomplishments in each research program area during FY 2025 is provided in Appendix B of this report.

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

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

On December 13, 2024, FDA posted the Office of Generic Drugs-authored impact story titled "Determining topical product bioequivalence with stimulated Raman scattering

[17] A detailed description of the FY 2025 GDUFA Science and Research Priority Initiatives can be found at www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects. The lists of research initiatives for earlier fiscal years are also available on FDA's Generic Drug Research Priorities and Projects web page.

microscopy."[18] The story described how researchers at FDA and Harvard Medical School collaborated on the conduct of a first-of-its-kind study that evaluated the use of noninvasive stimulated Raman scattering microscopy (SRS) to assess topical product bioavailability and bioequivalence. The study established the feasibility of the SRS technology to non-invasively measure the cutaneous pharmacokinetics of tazarotene in the skin when applied topically (in a manner similar to the way an MRI non-invasively images the body, but using different physical principles). In addition, the study was able to accurately confirm the comparable bioavailability of tazarotene from RLD and approved generic tazarotene cream products, and sensitively discriminate differences in the bioavailability of tazarotene from tazarotene gels compared to tazarotene creams. This groundbreaking research and development effort supported by the GDUFA research program demonstrated how cutting-edge scientific advances could be utilized to facilitate efficient, non-invasive assessments of bioequivalence for complex topical products, many of which were practically unfeasible to develop generics for before the advent of the GDUFA research program.

## F. FY 2025 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 June 3-4, 2025, FDA held the FY 2025 Generic Drug Science and Research Initiatives Public Workshop, which provided an overview of the status of the generic drug science and research program and an opportunity for public input in developing the FY 2026 research priorities. Information obtained during the public workshop and other inputs (e.g., comments to the public docket) were considered in developing the FY 2026 GDUFA Science and Research Priority Initiatives.[19]

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 2026 of certain details within the same eight priority areas mentioned above from FY 2025. 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

[18] Available at https://www.fda.gov/drugs/regulatory-science-action/determining-topical-product-bioequivalence-stimulated-raman-scattering-microscopy

[19] A detailed description of the FY 2026 GDUFA Science and Research Priority Initiatives can be found at www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects. The lists of research initiatives for earlier fiscal years are also available on FDA's Generic Drug Research Priorities and Projects web page.

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

A description of these topic areas and revised and expanded priorities is provided in the GDUFA Science and Research Priority Initiatives for FY 2026 on FDA's Generic Drug Research Priorities & Projects website.[20]

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

# V. Inspections Performance

FDA is committed to ensuring consistency and transparency regarding inspections.

This section satisfies the annual reporting commitment created by the GDUFA III Commitment Letter for FY 2025 to communicate final facility inspection activities for human generic drugs.

## A. GDUFA III Commitments

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

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

2. Median time from beginning of the inspection to the issuance of Form FDA 483 (483), *Inspectional Observations*;[21]

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.

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

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

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

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

- FDA conducts other types of inspections of facilities in which a conclusion of non-compliance may result in a delay or denial of application approval. Observations from inspections other than PAIs that can also impact an application's approvability include findings from 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.

- An Untitled Letter is not equivalent to a WL and is not included in this report.

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

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

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

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

Table 14 reflects the number of FY 2025 inspections[22] conducted by FDA in 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 14. Inspection Type by Location Totals

| | Location | | | |
|---|---|---|---|---|
| **Inspection Type** | Domestic | Foreign | Total* | Number of 483s Issued |
| PAI (API) † | 1 | 5 | 6 | 2 |
| PAI (API/FDF) † | 0 | 2 | 2 | 2 |
| PAI (FDF) † | 17 | 43 | 60 | 48 |
| PAI (Other) † | 7 | 9 | 16 | 12 |
| Surveillance (API) | 30 | 152 | 182 | 112 |

[22] FDA is not including in this section of this report 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 (MRA) or other MRAs. 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.

| | Location | | | |
|---|---|---|---|---|
| **Inspection Type** | Domestic | Foreign | Total* | Number of 483s Issued |
| Surveillance (API/FDF) | 5 | 12 | 17 | 16 |
| Surveillance (FDF) | 106 | 112 | 218 | 175 |
| Surveillance (Other) | 105 | 41 | 146 | 84 |
| BE Clinical† | 8 | 82 | 90 | 15 |
| BE Analytical† | 6 | 32 | 38 | 12 |

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

Table 15 shows the median time (in calendar days) between the start of inspections and the issuance of a 483 in FY 2025.

### Table 15. Median Time from Beginning of Inspection to 483 Issuance in FY 2025

| User Fee Program | FY 2025 Median Time (Calendar Days) |
|---|---|
| GDUFA | 5 |

Table 16 shows the median time (in calendar days) in FY 2025 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 16. Median Time from 483 Issuance to WL, IA, and Regulatory Meeting for Inspections with Final Classification of OAI (or Equivalent) (Calendar Days)

| User Fee Program | FY 2025 Median Time 483 to WL | FY 2025 Median Time 483 to IA | FY 2025 Median Time 483 to Reg. Meeting |
|---|---|---|---|
| GDUFA | 169 | 144 | 168 |

Table 17 shows the median time (in calendar days) between the issuance or holding of a WL, IA, and Regulatory Meeting and OAI resolution in FY 2025. “OAI resolution” includes the time to remediate CGMP issues at a site classified as OAI and the time for FDA to re-inspect the facility to confirm whether adequate remediation has taken place. The compliance action is considered resolved when the firm has sufficiently addressed the violations or deviations to allow the site to be reclassified by FDA as VAI or No

Action Indicated, and, in the case of an IA or a WL, the Agency has also removed the facility from the IA or closed the WL. This includes OAI resolution of WLs, IAs, and Regulatory Meetings that were issued or held in the reporting fiscal year. The same facility may receive more than one compliance action, for example a WL and an IA, following issuance of a 483. The OAI finalized date is when the facility was classified as OAI and is different from the date of issuance of a WL, IA, or Regulatory Meeting.

**Table 17. Median Time from Date of WLs, IAs, and Regulatory Meetings to Resolution of OAI Status (Calendar Days)**

| User Fee Program | FY 2025 Median Time OAI Finalized to Resolution | FY 2025 Median Time WL to OAI Resolution | FY 2025 Median Time IA to OAI Resolution | FY 2025 Median Time Reg. Meeting to OAI Resolution |
|---|---|---|---|---|
| GDUFA | 2048 | 945 | N/A | 1209 |

During FY 2025, there were 25 facilities that were issued a WL, IA and/or had a Regulatory Meeting with an OAI resolution occurring in or after FY 2025. 13 of these facilities were issued a WL, two were issued an IA, and 11 had Regulatory Meetings. Resolution includes the firm addressing the CGMP violations or deviations that resulted in the OAI outcome, as well as a reinspection and classification of the site as VAI or No Action Indicated, when appropriate.

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

## B. Inspection Efficiency Enhancements

The Agency has implemented various changes and continues to improve how it conducts inspections to verify pharmaceutical quality; the Agency also has improved transparency and timeliness in determining regulatory outcomes from inspections. In 2012, with the passage of the Food and Drug Administration Safety and Innovation Act,[23] Congress gave FDA the authority to enter into arrangements with a foreign government or an Agency of a foreign government to recognize foreign inspections after a determination that the foreign government has the capability to conduct inspections in accordance with section 809 of the FD&C Act. FDA currently has mutual recognition

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

agreements (MRAs)[24] 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 2025 by responding within 30 days of receipt to 108 requests for CGMP declarations. In addition to CGMP declarations, there are other ways that FDA is enhancing communication and transparency with foreign regulatory authorities regarding the compliance status of establishments in the United States. For example, foreign regulators can also find the CGMP status of an establishment by checking the inspection classification database[25] for the most recent inspection classification that is publicly available.

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

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

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

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

# VI. Continued Enhancement of User Fee Resource Management

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

**Table 18. FDA's Progress in Meeting the Continued Enhancement of User Fee Resource Management Commitments**

| Activity | Due Date/Deadline | Status |
|---|---|---|
| FDA to publish an implementation plan that describes how resource capacity planning and time reporting will continue to be utilized during GDUFA III. The plan will cover topics such as the continued maturation of resource capacity planning capability; the continual improvement of time reporting and its utilization in the Capacity Planning Adjustment (CPA); the integration of resource capacity planning in the Agency's resource and operational decision-making processes; and the implementation of the CPA, with a first year of adjustment for FY 2024 user fees. | By the end of the second quarter of FY 2023 | FDA published the implementation plan (https://www.fda.gov/media/166677/download?attachment) on March 29, 2023. |
| FDA to publish annual updates on its website on the Agency's progress relative to the activities detailed in the implementation plan. | By the end of the second quarter of each subsequent fiscal year | FDA published the first annual update to the implementation plan (https://www.fda.gov/media/186035/download?attachment) on March 31, 2025. |
| FDA will implement the CPA under the FD&C Act for the GDUFA Program with a first year of adjustment for FY 2024 fees. | Justification for the adjustment to be published in the *Federal Register* not later than 60 days before the start of the fiscal year | FDA implemented the CPA for FY 2024 fees and included a justification for this adjustment in the *Federal Register* notice publishing FY 2024 GDUFA fees (https://www.federalregister.gov/documents/2023/07/28/2023-16081/generic-drug-user-fee-rates-for-fiscal-year-2024) on July 28, 2023. |
| FDA will document in the annual GDUFA financial report how any fee revenues derived from the CPA are being utilized. | 120 days after the end of the fiscal year | GDUFA financial reports are published and posted at the following link: https://www.fda.gov/about-fda/user-fee-financial-reports/gdufa-financial-reports. The FY 2024 GDUFA financial report includes |

| Activity | Due Date/Deadline | Status |
|---|---|---|
| | | updates on the utilization of the fee revenues from the CPA. |
| By the end of FY 2025, an independent contractor to complete and publish an evaluation of the resource capacity planning capability. The evaluation findings and any related recommendations will be discussed at the FY 2026 GDUFA Five-Year Financial Plan public meeting. | Evaluation to be published by the end of FY 2025 | The independent evaluation[26] of the resource capacity planning capability was published on 9/26/2025.<br>The evaluation findings were discussed at the Financial Public Meeting[27] on 9/30/2025. |

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 19. FDA's Financial Transparency and Efficiency

| Activity | Due Date/Deadline | Status |
|---|---|---|
| FDA to publish a GDUFA Five-Year Financial Plan. | No later than the second quarter of FY 2023 | FDA published the FY 2023 GDUFA Five-Year Financial Plan (www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans) in April 2023. |
| FDA to publish updates to the GDUFA Five-Year Financial Plan. | No later than the second quarter of each subsequent fiscal year | FDA published the GDUFA III Five-Year Financial Plan – 2025 Update in July 2025 (available at https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans). |
| 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 () on September 30, 2025. |

[26] See https://www.fda.gov/media/188791/download?attachment
[27] See https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and

# VII. FY 2025 Performance Report Metrics

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

Table 20 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 20. Mean and Median Approval Times for Generic Drug Reviews**

| GDUFA III | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| **Receipt Cohort** | | | |
| Mean Approval Time (Calendar Days) | 533 | 411 | 271 |
| Median Approval Time (Calendar Days) | 511 | 380 | 270 |
| First Cycle Mean Approval Time (Calendar Days) | 391 | 364 | 271 |
| First Cycle Median Approval Time (Calendar Days) | 355 | 355 | 270 |
| Mean Tentative Approval Time (Calendar Days) | 583 | 441 | - |
| Median Tentative Approval Time (Calendar Days) | 554 | 442 | - |
| First Cycle Mean Tentative Approval Time (Calendar Days) | 435 | 405 | - |
| First Cycle Median Tentative Approval Time (Calendar Days) | 390 | 384 | - |
| Mean Number of ANDA Assessment Cycles to Approval | 2 | 1 | 1 |
| Median Number of ANDA Assessment Cycles to Approval | 2 | 1 | 1 |
| Mean Number of ANDA Assessment Cycles to Tentative Approval | 2 | 1 | - |
| Median Number of ANDA Assessment Cycles to Tentative Approval | 2 | 1 | - |
| Missed Goal Date for Original ANDAs by More Than 6 months | 24 | 2 | - |
| Missed Goal Date for Original ANDAs by More Than 9 months | 18 | 0 | - |
| Missed Goal Date for Original ANDAs by More Than 12 months | 12 | 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 21 and 22 summarize FDA's commitment to publish other metrics not already included in this report.

## Table 21. Fiscal Year Performance Report Metrics

| GDUFA III | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| **Application Receipt** | | | |
| Number of applications received[28] | 686 | 712 | 468 |
| Number of applications refused to receive | 37 | 21 | 17 |
| Average time to receipt decision (i.e., number of calendar days) | 39 | 39 | 38 |
| **ANDA Review** | | | |
| Number of ANDA applications received by FDA for standard assessment | 541 | 541 | 388 |
| Number of ANDA applications received by FDA for priority assessment | 145 | 171 | 80 |
| Percentage of ANDA proprietary name requests reviewed within 180 days of receipt | 81% | 83% | 89% |
| **Petitions** | | | |
| Beginning in FY 2024, number of suitability petitions submitted and assigned a goal | -- | 103 | 94 |
| Beginning in FY 2024, number of suitability petitions completed within 6 months after FDA completed the completeness assessment | --[29] | 99 | 55 |
| Beginning in FY 2024, percent of suitability petitions completed within 6 months after FDA completed the completeness assessment | -- | 96% | 100% |
| Number of citizen petitions to determine whether a listed drug has been voluntarily withdrawn from sale for reasons of safety or effectiveness pending a substantive response for more than 270 days from the date of receipt | 5 | 2 | 3 |
| **DMF** | | | |
| Number of DMF First Adequate Letters issued status (or equivalent) | 301 | 394 | 161 |
| **DMF Email Exchanges** | | | |
| Number of initial (first cycle) email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in DMF deficiency letters | 39 | 61 | 42 |

[28] Per 21 CFR 314.101(b)(1), an ANDA will be evaluated after it is submitted to determine whether the ANDA can be "received"; receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete.See FDA Guidance for Industry "***ANDA Submissions -- Refuse-to-Receive Standards" (December 2016)***. "

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

| GDUFA III | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Number of follow-up email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in follow-up cycle DMF deficiency letters | 8 | 9 | 2 |

## Table 22. GDUFA Meeting Management Initiatives

| GDUFA III | | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|---|
| FDA to grant or deny **Product Development Meeting** Requests within 14 calendar days from receipt of request* | Meetings Requested | 99 | 85 | 97 |
| | Meetings Granted | 71 | 69 | 81 |
| | Meetings Denied | 28 | 16 | 11 |
| | Meetings Conducted | 71 | 68 | 63 |
| FDA to grant or deny **Pre-Submission Meeting** Requests within 30 calendar days from receipt of request* | Meetings Requested | 9 | 3 | 7 |
| | Meetings Granted | 0 | 0 | 2 |
| | Meetings Denied | 9 | 3 | 5 |
| | Meetings Conducted | 0 | 0 | 2 |
| FDA to grant or deny a meeting request for a **Pre-Submission PSG Meeting** if the applicant within 14 days after receipt of the request has not submitted an ANDA* | Meetings Requested | 0 | 0 | 0 |
| | Meetings Granted | 0 | 0 | 0 |
| | Meetings Denied | 0 | 0 | 0 |
| | Meetings Conducted | 0 | 0 | 0 |
| FDA to conduct granted **PSG teleconferences** within 30 days of receipt* | Teleconference Requested | 2 | 1 | 3 |
| | Teleconference Granted | 2 | 1 | 1 |
| | Teleconference Denied | 0 | 0 | 2 |
| | Teleconference Conducted | 2 | 1 | 1 |
| FDA to grant or deny a meeting request for a **Post-Submission PSG Meeting** if the applicant has submitted an ANDA within 14 days after receipt of the request* | Meetings Requested | 0 | 0 | 0 |
| | Meetings Granted | 0 | 0 | 0 |
| | Meetings Denied | 0 | 0 | 0 |
| | Meetings Conducted | 0 | 0 | 0 |
| FDA to grant or deny a meeting request for an **MCRM*** | Meetings Requested | 1 | 6 | 6 |
| | Meetings Granted | 1 | 4 | 4 |
| | Meetings Denied | 0 | 2 | 2 |
| | Meetings Conducted | 1 | 4 | 4 |
| FDA to conduct an **EMCRM** within 90 calendar days after issuance of the last mid-cycle DRL* | Meetings Requested | 1 | 4 | 7 |
| | Meetings Granted | 0 | 4 | 6 |
| | Meetings Denied | 1 | 0 | 1 |
| | Meetings Conducted | 0 | 4 | 5 |
| FDA to provide a scheduled date for a requested **Post-CRL teleconference** within 14 calendar days of the request for a teleconference* | Teleconferences Requested | 64 | 72 | 65 |
| | Teleconferences Granted | 53 | 46 | 48 |
| | Teleconferences Denied | 11 | 25 | 16 |
| | Teleconferences Conducted | 53 | 46 | 46 |
| FDA to grant or deny **Post-CRL scientific meeting** requests within 14 days after receipt of the request* | Meetings Requested | 20 | 14 | 19 |
| | Meetings Granted | 14 | 10 | 14 |
| | Meetings Denied | 6 | 4 | 4 |

| GDUFA III | | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|---|
| | Meetings Conducted | 14 | 10 | 11 |
| FDA to strive to grant **DMF first cycle assessment deficiency teleconferences** | Teleconferences Requested | 4 | 1 | 5 |
| | Teleconferences Granted | 4 | 1 | 3 |
| | Teleconferences Denied | 0 | 0 | 1 |
| | Teleconferences Conducted | 0 | 0 | 1 |
| | Email exchanges in lieu of Teleconferences | 39 initial and 8 follow-ups | 61 initial and 9 follow-ups | 39 initial and 2 follow-ups |
| FDA to grant, deny, or defer in favor of re-inspection a **Post-WL Meeting** within 30 calendar days from receipt of request | Meetings Requested | 3 | 5 | 5 |
| | Meetings Granted | 2 | 5 | 2 |
| | Meetings Denied | 1 | 0 | 2 |
| | Meetings Conducted | 1 | 5 | 1 |
| When requested by the ANDA applicant, FDA will schedule a teleconference to clarify issues and answer questions on reclassifying a major amendment or standard review status. | Meetings Requested | 10 | 11 | 6 |
| | Meetings Granted | 10 | 11 | 6 |
| | Meetings Denied | 0 | 0 | 0 |
| | Meetings Conducted | 7 | 10 | 2 |

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

# VIII. Rationale for GDUFA Program Changes

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

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 3001(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 [since redesignated the Office of Inspections and Investigations], and the Office of the Commissioner;

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

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

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

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

The information below fulfills these reporting requirements.

## A. Changes in the Number of Individuals Hired as Agreed in the GDUFA III Commitment Letter, the Number of Remaining Vacancies, the Number of FTEs Funded by Fees Collected Pursuant to Section 744B, and the Number of FTEs Funded by Budget Authority by Division Within CDER, CBER, OII, and OC

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

### *1. Changes in the Number of Individuals Hired*

**Table 23. Number of Individuals Hired to Meet GDUFA III Commitments**

| Center | Number Hired in FY 2024 | Number Hired in FY 2025 | Change in Number Hired | Remaining Vacancies in FY 2024 | Remaining Vacancies in FY 2025 | Change in Number of Remaining Vacancies |
|---|---|---|---|---|---|---|
| CDER | 10 | 5 | -5 | 4 | 3 | -1 |
| CBER | N/A | N/A | N/A | N/A | N/A | N/A |
| OII* | 4 | 0 | -4 | 4 | 0 | -4 |
| OC | N/A | N/A | N/A | N/A | N/A | N/A |
| Total | 14 | 5 | -9 | 8 | 3 | -5 |

*Note: In the FY25 FDA Re-Organization, 4 GDUFA vacancies (compliance officers) moved to CDER--when the compliance function moved out of OII.

FDA committed to hiring 128 individuals in FY 2023. FDA has hired 125 of 128 GDUFA III FTEs as of September 30, 2025.

### *2. Changes in the Number of FTEs Funded by Budget Authority and Number of FTEs Funded by Fees by Division Within CDER, CBER, OII, and OC*

The data in Table 24 show the changes in the number of FTEs funded by GDUFA fees collected and the number of FTEs funded by budget authority in FY 2024 by each division within CDER, CBER, OII, 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, OII, and OC. FDA uses a 2,080-hour workload to equate to one FTE, and this calculation is reflected in Table 24. The number of FTEs funded by budget authority for FY 2025 are those FTEs as of September 30, 2025.

## Table 24. Changes in the Number of FTEs Funded by GDUFA Fees and by Budget Authority

| Center and Office | Number of FTEs Funded by Budget Authority in FY 2024† | Number of FTEs Funded by Budget Authority in FY 2025† | Change in the Number of FTEs Funded by Budget Authority† | Number of FTEs Funded by Fees in FY 2024† | Number of FTEs Funded by Fees in FY 2025† | Change in the Number of FTEs Funded by Fees† |
|---|---|---|---|---|---|---|
| CDER | | | | | | |
| Office of Communications | 5.70 | 8.31 | 2.61 | 24.13 | 18.60 | -5.52 |
| Office of Compliance | 20.21 | 21.81 | 1.60 | 58.31 | 58.02 | -0.29 |
| Office of the Center Director | 3.19 | 1.73 | -1.46 | 7.91 | 9.23 | 1.32 |
| Office of Executive Programs | 6.87 | 3.86 | -3.00 | 22.51 | 18.08 | -4.44 |
| Office of Generic Drugs | 11.82 | 21.99 | 10.17 | 536.02 | 519.56 | -16.46 |
| Office of Medical Policy | 0.00 | 0.30 | 0.30 | 0.20 | 0.00 | -0.20 |
| Office of Management | 5.41 | 9.12 | 3.71 | 54.64 | 47.17 | -7.47 |
| Office of New Drugs | 1.61 | 1.72 | 0.11 | 0.00 | 0.00 | 0.00 |
| Office of Pharmaceutical Quality | 27.81 | 65.42 | 37.61 | 662.99 | 620.98 | -42.01 |
| Office of Regulatory Policy | 2.48 | 6.12 | 3.64 | 6.24 | 5.12 | -1.11 |
| Office of Surveillance and Epidemiology | 7.03 | 6.24 | -0.79 | 67.42 | 64.04 | -3.38 |
| Office of Strategic Programs | 7.12 | 3.14 | -3.98 | 70.27 | 65.03 | -5.24 |
| Office of Information Management and Technology | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Office of Translational Sciences | 24.15 | 20.25 | -3.90 | 59.49 | 63.31 | 3.82 |
| Other Offices | 0.85 | 0.00 | -0.85 | 1.22 | 0.00 | -1.22 |
| Working Capital Fund* | 30.90 | 30.31 | -0.59 | 105.55 | 104.12 | -1.43 |
| CBER | | | | | | |
| Office of Biostatistics and Pharmacovigilance | 0.03 | 0.01 | -0.02 | 0.00 | 0.00 | 0.00 |
| Office of Blood Research and Review | 0.78 | 0.55 | -0.23 | 0.00 | 0.00 | 0.00 |
| Office of Compliance and Biologics Quality | 0.22 | 0.29 | 0.07 | 0.00 | 0.00 | 0.00 |

| Center and Office | Number of FTEs Funded by Budget Authority in FY 2024† | Number of FTEs Funded by Budget Authority in FY 2025† | Change in the Number of FTEs Funded by Budget Authority† | Number of FTEs Funded by Fees in FY 2024† | Number of FTEs Funded by Fees in FY 2025† | Change in the Number of FTEs Funded by Fees† |
|---|---|---|---|---|---|---|
| Office of Therapeutic Products | 0.00 | 0.02 | 0.02 | 0.00 | 0.00 | 0.00 |
| Office of Vaccines Research and Review | 0.01 | 0.00 | -0.01 | 0.00 | 0.00 | 0.00 |
| Office of Communication Outreach and Development | 0.06 | 0.04 | -0.02 | 0.00 | 0.00 | 0.00 |
| Office of the Center Director | 0.04 | 0.04 | 0.00 | 0.00 | 0.00 | 0.00 |
| Office of Regulatory Operations | 0.08 | 0.07 | -0.01 | 0.00 | 0.00 | 0.00 |
| Office of Management | 0.13 | 0.08 | -0.05 | 0.00 | 0.00 | 0.00 |
| Office of Information Management and Technology | 0.01 | 0.00 | -0.01 | 0.00 | 0.00 | 0.00 |
| Working Capital Fund* | 0.05 | 0.04 | -0.01 | 0.00 | 0.00 | 0.00 |
| OC | | | | | | |
| OC of the Commissioner - Immediate Office | 1.98 | 4.57 | 2.59 | 7.79 | 4.39 | -3.40 |
| Office of the Chief Counsel | 6.8 | 24.59 | 17.79 | 26.73 | 23.61 | -3.12 |
| Office of the Chief Medical Officer | 0.00 | 1.80 | 1.80 | 0.00 | 1.73 | 1.73 |
| Office of the Chief Scientist | 0.22 | 4.25 | 4.03 | 0.86 | 4.08 | 3.22 |
| Office of Clinical Policy and Programs | 0.17 | 0.00 | -0.17 | 0.66 | 0.00 | -0.66 |
| Office of Digital Transformation | 0.09 | 0.00 | -0.09 | 0.34 | 0.00 | -0.34 |
| Office of Enterprise Management Services | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Office of External Affairs | 1.32 | 4.55 | 3.23 | 5.17 | 4.37 | -0.80 |
| Office of Global Policy and Strategy | 3.84 | 18.67 | 14.83 | 15.09 | 17.92 | 2.83 |
| Office of Operations | 3.39 | 0.93 | -2.46 | 13.32 | 0.89 | -12.43 |
| Office of Policy, Legislation, and International Affairs | 3.95 | 13.55 | 9.60 | 15.53 | 13.01 | -2.53 |
| Working Capital Fund* | 7.61 | 9.34 | 1.73 | 11.43 | 14 | 2.57 |
| OII | | | | | | |
| Office of Pharmaceutical Quality Operations | 0.00 | 0.00 | 0.00 | 320.32 | 196.25 | -124.07 |

| Center and Office | Number of FTEs Funded by Budget Authority in FY 2024† | Number of FTEs Funded by Budget Authority in FY 2025† | Change in the Number of FTEs Funded by Budget Authority† | Number of FTEs Funded by Fees in FY 2024† | Number of FTEs Funded by Fees in FY 2025† | Change in the Number of FTEs Funded by Fees† |
|---|---|---|---|---|---|---|
| Working Capital Fund* | 21.51 | 14.04 | -7.47 | 19.93 | 15.34 | -4.59 |

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

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

FDA reported a decrease in overall FTEs funded by budget authority in FY 2025 compared to FY 2024. The decrease in reported FTEs was attributable in part to a re-baselining of payroll distribution percentages between annual appropriations and GDUFA fees, as well as a major reorganization of OII implemented in FY 2025.

## 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 25 provides data for the GDUFA fee revenue amounts, the FY 2024 and FY 2025 total average cost per FTE in the generic drug review program, and the changes in these costs from FY 2024 to FY 2025.

In FY 2025, FDA had net collections of $620,713,654 in human generic drug user fees, spent $578,056,138 in user fees for human generic drug activities, and carried a cumulative balance of $140,512,273 forward for future fiscal years. Detailed financial information for the GDUFA user fee program can be found in the FY 2025 GDUFA financial report.

The target revenue amount for FY 2025 for GDUFA III was $638,962,000. For FY 2025, this amount included an inflation adjustment of $25,423,788 and a capacity planning adjustment of $0.

FDA may, in addition to the inflation and capacity planning adjustments, apply the operating reserve adjustment under section 744B(c)(3) of the FD&C Act to further

increase the target revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section. If the estimated carryover balance exceeds 12 weeks of operating reserves, FDA is required to decrease fees for that fiscal year to reduce the operating reserve to not more than 12 weeks. No operating reserve adjustment was made in the setting of FY 2025 fees.

In FY 2025, GDUFA review process costs had a small increase compared to FY 2024.

**Table 25. GDUFA Fee Revenue Amounts, the FY 2024 and FY 2025 Total Average Cost Per FTE, and the Changes in These Costs from FY 2024 to FY 2025**

| Revenue/Cost | FY 2024 | FY 2025 | Change from FY 2024 to FY 2025 |
|---|---|---|---|
| Fee Revenue Amounts (Net Collections) | $569,359,591 | $620,713,654 | 9% |
| Cost of Activities | $758,357,084 | $733,797,813 | -3% |
| Changes in average total cost per FTE | $206,590 | $221,802 | 7% |

## 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, OII, and OC, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required. Accordingly, Table 26 provides the number of employees within CDER, CBER, OII, and OC who are required to report their time and those who are not required to report their time as of September 30, 2025.

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

**Table 26. Time Reporting Requirement for FY 2025**

| Center | FTEs for Whom Time Reporting Is Required | FTEs for Whom Time Reporting Is Not Required |
|---|---|---|
| CDER | 4,951 | 0 |
| CBER | 1,149 | 0 |
| OII | 2,901 | 0 |
| OC | 61 | 2,343 |
| Total | 6,161 | 2,343 |

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

Section 744C(a)(3) of the FD&C Act requires that FDA provide data, analysis, and discussion of the changes in the average FTE hours required to complete review of each type of ANDA.[30]

### Table 27. Average FTE Hours Required to Complete Review

| Application Type | Hours Required to Complete Application Reviews FY 2024 | Hours Required to Complete Application Reviews FY 2025 | Change from FY 2024 to FY 2025 |
|---|---|---|---|
| Original ANDAs Submitted | 1,385 | 1,663 | 278 |
| Total | 1,385 | 1,663 | 278 |

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 2022 to FY 2024 and FY 2023 to FY 2025). The sum was then divided by the total number of applications over the same 3-year period.

[30] 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.

# Appendix A: Definitions of Key Terms

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

A. **Act on an Application** - means that FDA will issue a CRL, an approval letter, a tentative approval 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 of it merits further clarification.

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

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

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

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

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

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

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

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

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

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

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

    a. Prior to ANDA submission;
    b. After a PSG Teleconference if a prospective applicant or applicant seeks further feedback from FDA;
    c. After issuance of a complete response letter 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BB. **Major Amendment** – GDUFA III Commitment Letter - means a Major Amendment as described in the guidance for industry *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA* (September 2024) and any subsequent revision.[1]

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

CC. **Minor Amendment** – GDUFA III Commitment Letter - means a minor amendment as described in the guidance for industry on *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA* (September 2024) and any subsequent revision.[2]

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

EE. **Pre-Submission Meeting** – As described in the guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* (October 2022),[3] means a meeting in which an applicant has an opportunity to present unique or novel data or information that will be included in the ANDA submission such as formulation, key studies, justifications, and/or methods used in product development, as well as the interrelationship of the data and information in the ANDA. Although the proposed content of the ANDA will be discussed, Pre-Submission Meetings will not include a substantive review of summary data or full study reports.

FF. **Prior Approval Supplement (PAS)** - means a request to the Secretary of Health and Human Services to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved ANDA when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.[4]

GG. **Priority** - means submissions affirmatively identified as eligible for expedited assessment pursuant to CDER's MAPP 5240.3, *Prioritization of the Review of Original ANDAs, Amendments and Supplements*, as revised.[5]

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

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

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[2] See www.fda.gov/regulatory-information/search-fda-guidance-documents.
[3] See www.fda.gov/regulatory-information/search-fda-guidance-documents.
[4] See section 744A(11) of the FD&C Act.

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

JJ. **Refuse to Receive (RTR)** - means refusal to receive an ANDA for review. See 21 CFR 314.101 and the guidance for industry *ANDA Submissions – Refuse-to-Receive Standards* (December 2016).[6]

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

LL. **Standard** - means submissions not affirmatively identified as eligible for expedited assessment pursuant to the CDER's MAPP 5240.3, *Prioritization of the Review of Original ANDAs, Amendments and Supplements*, as revised.[7].

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

NN. **Submission date** - means the date that a generic drug submission or Type II DMF is deemed to be "submitted" pursuant to Section 744B(a)(6) of the FD&C Act, which states that a generic drug submission or Type II DMF is deemed to be "submitted" if it is submitted via an FDA electronic gateway, on the day when transmission to that electronic gateway is completed, except that, when the submission or DMF arrives on a weekend, Federal holiday, or day when the FDA office that will review that submission is not otherwise open for business, the submission shall be deemed to be submitted on the next day when that office is open for business. In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements in guidance. Refer to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (September 2024).[8]

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

PP. **Tentative Approval (TA) Letter** - If an ANDA meets the substantive requirements for approval but cannot be approved because of a patent or exclusivity issue, FDA

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

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

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

issues a TA letter to the applicant, and the TA letter details the basis for the tentative approval. 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 tentative approval does not allow the applicant to market the generic drug product.

QQ. **Type II API Drug Master File (DMF)** - A submission of information to FDA concerning the manufacture of a pharmaceutical active ingredient by a person that intends to authorize FDA to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

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

# Appendix B: Synopsis of FY 2025 GDUFA Science and Research Accomplishments

GDUFA-funded research aims to improve the efficiency with which generic drugs can be developed and assessed, and this research benefits public health by making it more feasible for manufacturers to develop generic drugs, which can reduce the risk of drug shortages and facilitate competition. This research is intended to enhance patient access to drug treatment by helping make these products more widely available, which may help patients in the United States to obtain medicines they need. Multiple resources for public input, including the *Federal Register* notice (public docket FDA-2023-N-0119[1]) opened for public comments, as well as input shared at the Fiscal Year 2025 Generic Drug Science and Research Initiatives Public Workshop[2] helped FDA, in collaboration with industry and academia stakeholders, to identify eight GDUFA Science and Research Priority Initiatives for FY 2025[3] that could expand and accelerate patient access to generic drugs. Summarized below are a selection of highlighted accomplishments in each of the eight priority areas that illustrate the types of scientific insights being developed, as well as a ninth area highlighting additional generic drug science and research during FY 2025. More detailed information in all nine areas is provided in the FY 2025 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 2025. These outcomes include general guidances for industry and PSGs published in FY 2025 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 2025 focused on understanding how ingredients in drug products may either contribute to or mitigate the formation of potentially harmful impurities such as nitrosamine adducts (e.g., nitrosamine drug substance-related impurities (NDSRIs)), evaluating the risk of human exposure to these impurities, and developing methods for abbreviated new drug application (ANDA) applicants to efficiently address the potential risks.

[1] See https://www.regulations.gov/document/FDA-2023-N-0119-0008.

[2] See https://www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2025-generic-drug-science-and-research-initiatives-public-workshop-06032025.

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

During FY 2025, FDA conducted internal research studies and funded external research collaborations to 1) advance safety assessment methodologies through enhanced mutagenicity testing, 2) elucidate mechanisms of NDSRI formation and develop mitigation strategies for various drug substances, 3) establish robust analytical detection methods, and 4) facilitate an approach to support industry-wide implementation of an efficient approach by which to address potential concerns associated with NDSRIs. A notable outcome of this research was the development of a provisional Biopharmaceutics Classification System (BCS) classification framework specifically for nitrosamine-impacted drug products. This framework provides FDA reviewers with standardized tools and centralized resources, enhancing review consistency and efficiency by eliminating the need for individual BCS assessments across different offices. Additionally, FDA developed a four-tier risk-based evaluation framework for BCS Class IV drug products, which present unique challenges due to their low solubility and permeability characteristics. This framework provides a potential approach for establishing bioequivalence without in vivo studies for nitrosamine-impacted BCS Class IV drugs when reformulations involve antioxidants or pH modifiers with a limited impact on absorption.

Another significant accomplishment was the advancement of safety testing methodologies through the development of an Enhanced Ames Test (EAT) for evaluating nitrosamine mutagenicity. The EAT demonstrated extremely high sensitivity and moderate specificity for identifying carcinogenic nitrosamines, addressing limitations of standard Ames testing. FDA also developed complementary in vitro mammalian cell assays using human TK6 cell lines and HepaRG cells with endogenous metabolic activity, providing more human-relevant safety assessment tools. These research efforts directly supported FDA's September 2024 revised guidance on "Control of Nitrosamine Impurities in Human Drugs," which introduced FDA recommendations for alternative bioequivalence approaches for reformulated products, helping reduce the potential need for costly and time-consuming clinical studies while maintaining required patient safety standards.

## B. Complex Active Ingredients

The advancement of research in this area during FY 2025 focused on improving orthogonal methods for the characterization of chemical compositions, molecular structures, and distributions of complex active pharmaceutical ingredients (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 their performance, thereby supporting the development of efficient characterization-based bioequivalence and pharmaceutical equivalence approaches.

During FY 2025, FDA conducted internal research studies and funded external research collaborations to develop modern state-of-the-art analytical methods to characterize complex APIs with diverse structures and complex impurities resulting from process differences. A notable outcome of this research was the development of a rapid and accurate $^{31}$P quantitative nuclear magnetic resonance (qNMR) method for a direct assay of oligonucleotides in drug products. This approach offers improved accuracy and flexibility compared to conventional UV absorbance methods, particularly for phosphorodiamidate morpholino oligomers such as eteplirsen. The method also enables the assessment of critical quality attributes (CQAs), impurity profiling, and diastereoisomer distribution analysis, which are important for regulatory evaluation.

Another significant accomplishment was the advancement of immunogenicity risk assessment methodologies for peptide and oligonucleotide products. FDA developed functional assays designed to assess whether impurities can activate innate immune responses, demonstrating high sensitivity to pattern recognition receptor-engaging impurities. These assays can detect a wide range of model agonists in the presence of peptides with sensitivity up to 0.001% of total product mass. This research directly supported the approval of multiple first generic complex peptide products, including liraglutide (3 approvals), exenatide (1 approval), and glucagon (2 approvals), demonstrating how advanced analytical characterization methods enable more efficient regulatory pathways for complex generic products while ensuring patient safety and therapeutic equivalence.

## C. Complex Dosage Forms and Formulations

The advancement of research in this area during FY 2025 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 CQAs that control how these complex dosage forms and formulations work, and to develop suitable test methods for characterizing and comparing these CQAs in a reference listed drug (RLD) product and in a prospective generic product.

During FY 2025, FDA conducted internal research studies and funded external research collaborations to 1) continue developing new analytical methods for the characterization of complex polymeric excipients in LAI formulations, 2) advance imaging technologies, develop in vitro release test methods, and 3) create physiologically based pharmacokinetic (PBPK) models for LAI products. A notable outcome of this research was the development of a predictive semi-empirical model for ethylene vinyl acetate (EVA)-based solid implants that can predict real-time drug release profiles for up to 3.5 years using only 3-month drug release data. This advancement provides valuable insights for developing accelerated in vitro release testing as a reliable surrogate for comprehensive real-time assessments in generic drug development, where extended

release periods of up to 3+ years present significant testing challenges. Another significant accomplishment was the establishment of mechanistic in vitro-in vivo correlations (IVIVCs) for multiple LAI suspension products, including medroxyprogesterone acetate, paliperidone palmitate, and aripiprazole lauroxil. These validated mechanistic IVIVCs have the potential to enable streamlined alternative bioequivalence methodologies that may reduce the reliance on costly and lengthy comparative clinical endpoint bioequivalence studies.

For nanotechnology products, FDA advanced the understanding of CQAs that determine lipid nanoparticle performance, and developed improved characterization methods using asymmetrical flow field-flow fractionation (AF4) with multi-detection capabilities. These research efforts supported the approval of multiple generic nanomaterial-containing products in FY 2025, including amphotericin B liposome injections, paclitaxel protein-bound particles, and iron sucrose injections. For example, FDA approved the first generic iron sucrose injections (referencing Venofer®) on August 8, 2025. Simultaneous approvals on that day for three generic manufacturers of this complex product ended nearly a decade of challenges that had limited patient access to generic versions of these therapeutically important iron-based medicines. Through targeted GDUFA research, FDA was able to resolve difficult technical questions about iron carbohydrate active ingredients, and generated crucial scientific insights that enhanced FDA's ability to evaluate the data submitted in ANDAs. The FDA's comprehensive research efforts in this area not only facilitated these noteworthy approvals, they also established important benchmarks that now enable the efficient assessment of similar pharmaceutical products, demonstrating how FDA's internal research capabilities are often essential to help address regulatory challenges and to expand treatment options for patients.

## D. Complex Routes of Delivery

The advancement of research in this area during FY 2025 focused on improving efficient characterization-based bioequivalence approaches for locally acting gastrointestinal, buccal, sublingual, inhalation, nasal, ophthalmic, otic, 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 2025, FDA conducted internal research studies and funded external research collaborations to investigate multiple aspects of products with complex routes of delivery. For locally acting gastrointestinal products, research focused on developing and validating PBPK models that integrate in vitro dissolution testing under physiologically relevant conditions with in silico modeling to establish in vitro-in vivo

relationships for products like budesonide, sulfasalazine, and mesalamine. For inhalation products, research concentrated on refining PSG recommendations to provide options for more efficient bioequivalence approaches as alternatives to comparative clinical endpoint bioequivalence studies; these efficient alternatives are supported by advanced characterization methods including high-speed imaging, optical coherence tomography, and morphologically directed Raman spectroscopy, and were developed based upon FDA's extensive research in this area.

A notable outcome of the research on ophthalmic products was the development of an integrated analytical framework for dexamethasone intracanalicular inserts that addressed challenges associated with sourcing excipients from different suppliers and that linked excipient source and architecture to crosslinking capacity, microstructure, swelling kinetics, and drug release. This information-rich characterization approach identified practical CQAs and surrogate indicators of network-forming potential and product performance that can support Q3-based bioequivalence approaches for hydrogel inserts. This analytical framework has the potential to support efficient bioequivalence approaches even when direct compositional sameness after curing cannot be reliably demonstrated, dramatically improving the feasibility of developing generic versions of such products.

For topical products, research designed to evaluate how changes in Q3 attributes of semisolid dosage forms may impact bioequivalence and therapeutic equivalence (including sensorial properties such as a cooling sensation) showed that the Q3 characterization tests recommended in PSGs for topical products are generally more sensitive than human perception, and helped to establish how different the Q3 attributes could be before they were perceptible. In parallel, complementary research with mechanistic skin absorption models predicted bioavailability based upon product quality (Q3) testing and in vitro permeation testing data, enabling efficient virtual bioequivalence assessments that consider potential failure modes for bioequivalence as a function of the Q3 attributes of the drug product. These research projects illustrated how advanced characterization methods and modeling approaches, together, can overcome constraints on formulation design that can limit the potential for topical generic products to utilize efficient bioequivalence approaches, and that have otherwise made it challenging to develop many other generic products administered via complex routes of delivery. Such research, to expand the potential for more complex generic products to utilize efficient bioequivalence approaches, can substantially help to enhance patient access to many important medicines with complex routes of delivery.

## E. Complex Drug-Device Combination Products

The advancement of research in this area during FY 2025 focused on enhancing the efficiency of equivalence approaches for complex drug-device combination products (DDCPs). This focus involved evaluating the impact of identified differences between

the RLD and a prospective generic product's user interface, hardware, software, or propellant on the bioequivalence, therapeutic equivalence, substitutability, or post-marketing safety profile of the DDCP.

During FY 2025, FDA conducted internal research studies and funded external research collaborations to evaluate how differences in the device constituent between an RLD and prospective generic DDCP could impact product performance and cause use errors. This included completing a comparative use human factors (CUHF) study that evaluated "other" design differences between semi-automated and manual pen injector platforms. The study successfully demonstrated the feasibility of using a non-inferiority framework to assess use error rates and success rates, providing critical evidence that certain design differences do not compromise patient safety or therapeutic outcomes. Statistical analyses demonstrated non-inferiority of the test product to the RLD for both dose selection and injection tasks, within a pre-specified non-inferiority margin. Another significant accomplishment was the finalization of a visual taxonomy system for DDCP user interface elements that systematically categorizes design features and identifies attributes most likely to contribute to use errors on critical tasks. This taxonomy provides evaluators with a standardized tool to assess the impact of design differences on substitutability between generic products and their RLDs, creating a common terminology for design features and facilitating more consistent regulatory assessments.

Separate research during FY 2025 advanced the development of efficient in vitro test methods for assessing the adhesion performance of transdermal and topical delivery systems (collectively, TDS). This research provided meaningful insights that can inform the development of generic TDS, and ongoing research in this area is focused on developing in vitro test methods with the goal of reducing the need for additional in vivo studies in humans over the lifecycle of the product. These research initiatives with DDCPs are contributing to a modernized assessment approach and developing innovative new scientific tools that reduce development uncertainty, provide validated methodological frameworks, and enable more efficient pathways for developing high quality, safe and effective generic DDCPs.

## F. Oral and Parenteral Generic Products

The advancement of research in this area during FY 2025 focused on 1) understanding how ingredients in oral and parenteral drug products may modulate bioavailability and 2) improving biorelevant dissolution methods and in silico models to support the expansion of Biopharmaceutics Classification System-based biowaivers and to support the global harmonization of regulatory standards for oral drug products. This research included exploring how to manage potential risks related to subject safety more consistently when developing clinical bioequivalence study recommendations, and also included research to elucidate 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 2025, FDA conducted internal research studies and funded external research collaborations to develop bio-predictive in vitro methods to evaluate the impact of different product designs, food effects, and drug-drug interactions on the assessment of bioequivalence, as well as evaluating the substitutability of generic oral drug products. A notable outcome of this research was the mechanistic understanding of alcohol-induced dose dumping effects in controlled-release oral dosage forms. This research demonstrated that osmotic system-based extended-release formulations of carbamazepine resist dose dumping due to the slow rate at which their polymers dissolve in alcohol, while matrix systems based on other polymers may be susceptible to dose dumping (depending on their alcohol solubility characteristics). This research meaningfully informed the design of generic drugs by elucidating the interplay between the physicochemical properties of drug, the rate controlling agent, and other factors that can impact alcohol dose dumping. These technical insights help ensure the safety of generic drugs for patients, particularly for drugs with narrow therapeutic indices.

Another significant accomplishment was the advancement of physiologically based pharmacokinetic (PBPK) modeling capabilities for amorphous solid dispersion (ASD) products. This research developed and validated comprehensive frameworks to predict formulation-dependent food effects, successfully demonstrating that mechanistic models can distinguish between products showing positive versus negative food effects. For example, the research correctly predicted that Sempera® exhibits a positive food effect while Tolsura® shows a negative food effect, despite both being itraconazole ASD formulations. These modeling advances support the potential for efficient model-based biowaivers that would reduce the need for clinical fed-state bioequivalence studies, streamlining generic drug development to accelerate patient access to generic medicines, while maintaining rigorous regulatory standards. The research also supported global harmonization efforts through a comprehensive assessment of bioequivalence recommendations, contributing to the implementation of ICH M13A guidelines that have substantially streamlined generic drug development for the most common class of drug products that FDA approves for patients.

## G. Model Integrated Evidence (MIE) of Bioequivalence

The advancement of research in this area during FY 2025 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.

Another significant accomplishment was the establishment of mechanistic in vitro-in vivo correlations for LAI suspension products, including paliperidone palmitate, using validated PBPK models that leveraged mechanistic deconvolution methods. The research successfully predicted plasma concentrations for both preclinical and human models based on in vitro dissolution profiles. For orally inhaled drug products, research resulted in the publication of five new and six revised PSGs that included detailed recommendations for using mechanistic modeling to support bioequivalence determinations, that may help reduce the need for comparative clinical endpoint studies, thereby making it substantially more feasible to develop generic inhalation products that are widely used by patients but currently challenging to develop as generics.

These research projects demonstrate how MIE approaches can overcome technical constraints that have otherwise made it unfeasible to develop many complex generic products, while also reducing development costs and accelerating patient access to these important medicines.

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

The advancement of research in this area during FY 2025 focused on building systems and infrastructure that support the functionality of artificial intelligence (AI) and machine learning (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 large language models 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 2025, FDA conducted internal research studies that included the development of an agentic AI system for automating maximum daily dose (MDD) determinations from drug labels. The system utilizes specialized AI agents working sequentially to collect relevant information from the drug label, identify dosing scenarios, calculate MDD values based on FDA guidelines, and provide determinations. Testing on 164 drug products demonstrated a 91.5 percent consistency overall, with the system generating responses in structured format with detailed documentation including source quotes, calculation steps, and reasoning processes for thorough verification by reviewers.

Another significant accomplishment was the advancement of AI-assisted image analysis methodologies for characterizing critical microstructure attributes in complex

pharmaceutical formulations. The AI-enhanced analytical approaches demonstrated the ability to accurately assess API particle distribution and oil droplet characterization in emulsion-based systems, addressing deficiencies identified in conventional microstructure characterization methods for gel formulations. These AI/ML tools have the potential to significantly enhance the efficiency, comprehensiveness, and consistency of regulatory assessments, modernizing the generic drug evaluation processes to help enhance patient access to generic drugs.

## I. Other Generic Drug Science and Research

Other generic drug science and research during FY 2025 focused on addressing generic drug development challenges, particularly for orphan products and alternative bioequivalence approaches for generic drugs for which FDA authority permits certain differences from the RLD under an approved suitability petition (petitioned drugs).[4]

During FY 2025, FDA conducted research to identify factors influencing the development of generic orphan drug products and to help facilitate use of suitability petitions, as appropriate. A notable outcome of this research was the application of machine learning methodology using Random Survival Forest analysis to predict the timing of ANDA submissions for orphan drugs. The analysis of 140 New Chemical Entity (NCE) and 97 non-NCE orphan drugs approved between 2008-2023 revealed distinct drivers for each product category: economic incentives (sales revenue and units sold) were found to be the key drivers for orphan drug products with NCEs to be developed as generics. Yet, regulatory clarity (particularly the availability of a PSG) was the key driver for developing generic versions of non-NCE orphan drug products. These insights, demonstrating that FDA can influence the availability of certain generic orphan drug products by developing PSGs for them, provides actionable intelligence for FDA regulatory planning, including PSG prioritization and resource allocation.

Another significant accomplishment was the development of standardized assessment approaches for petitioned drugs. FDA published six PSGs for petitioned drugs through a proactive approach that provides immediate regulatory clarity before first ANDA approvals. These guidances introduced FDA recommendations for a standardized dual-option approach covering new dosage forms approved through suitability petitions, including orally disintegrating tablets, chewable tablets, and oral suspensions. The guidances directly addressed industry requests from numerous controlled correspondences, demonstrating FDA's responsiveness to real-world development challenges. These outcomes demonstrate the substantial impact of FDA's generic drug research program on reducing regulatory challenges and increasing the efficiency of generic product development, ultimately facilitating timely access to medically

[4] See 505(j)(2)(C) of the FD&C Act and 21 CFR 314.93.

necessary generic drugs that address critical public health needs and help mitigate the risk of drug shortages.

# Appendix C: Analysis of Performance in Meeting Goals

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

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

Although the mandate is to report the number of ANDAs filed, the term "received" is used instead of "filed" in the statute with respect to ANDAs. FDA will thus report on the aggregate number of ANDAs received. Per 21 CFR 314.101(b)(1), an ANDA will be reviewed after it is submitted to determine whether the ANDA can be "received." "Receipt of an ANDA" means that FDA made a threshold determination that the ANDA is substantially complete. A "substantially complete ANDA" is an ANDA that on its face is sufficiently complete to permit a substantive review.[1] "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, C-2 and C-3 do not account for submissions that were determined to not be substantially complete.

[1] See FDA Guidance for Industry "***ANDA Submissions -- Refuse-to-Receive Standards*** **(December 2016)**.

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

| Goal Type | Review Goal | Received | Received with Goal Post FY 2023 | Approved | Tentatively Approved | Complete Response | Missed Goal* | Percent on Time† | Potential Range†T | On Time Imminent Approval† | Imminent Approval Potential Range† |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **I. Original ANDA Review** | | | | | | | | | | | |
| Standard Original ANDA Submissions | 10/30 months | 542 | 489 | 95 | 21 | 425 | 48 | 92% | 92% to 92% | 94% | 94% to 94% |
| Priority Original ANDA Submissions | 8/10/30 months | 145 | 126 | 40 | 2 | 102 | 18 | 88% | 88% to 88% | 93% | 93% to 93% |

* 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, tentative approval, and CR actions.

‡ This table provides updated performance data for the FY 2023 performance goals that were reported as open in last year's performance report.

## Table C-2. FY 2024 Updated Performance by Goal Type‡

| Goal Type | Review Goal | Received | Received with Goal Post FY 2024 | Approved | Tentatively Approved | Complete Response | Missed Goal* | Percent on Time† | Potential Range† | On Time Imminent Approval† | Imminent Approval Potential Range† |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **I. Original ANDA Review** | | | | | | | | | | | |
| Standard Original ANDA Submissions | 10/30 months | 541 | 509 | 86 | 36 | 355 | 35 | 93% | 84% to 94% | 97% | 87% to 97% |
| Priority Original ANDA Submissions | 8/10/30 months | 172 | 158 | 33 | 5 | 118 | 7 | 94% | 87% to 95% | 97% | 89% to 97% |
| **II. Amendment Review** | | | | | | | | | | | |
| Standard Major ANDA Amendments | 8/10 months | 587 | 418 | 132 | 42 | 397 | 37 | 94% | 91% to 94% | 96% | 94% to 96% |
| Priority Major ANDA Amendments | 6/8/10 months | 111 | 66 | 36 | 4 | 71 | 16 | 86% | 86% to 86% | 86% | 86% to 86% |
| Standard and Priority Minor ANDA Amendments | 3 months | 817 | 304 | 397 | 129 | 285 | 120 | 85% | 85% to 85% | 96% | 95% 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, tentative approval, and CR actions.

‡ This table provides updated performance data for the FY 2024 performance goals that were reported as open in last year's performance report.

### Table C-3. FY 2025 Preliminary Performance by Goal Type

| Goal Type | Review Goal | Received | Received with Goal Post FY 2025 | Approved | Tentatively Approved | Complete Response | Missed Goal* | Percent on Time†† | Potential Range†† | On Time Imminent Approval† | Imminent Approval Potential Range† |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **I. Original ANDA Review** | | | | | | | | | | | |
| Standard Original ANDA Submissions | 10/30 months | 389 | 375 | 1 | 0 | 15 | 1 | 97% | 7% to 99% | 100% | 7% to 100% |
| Priority Original ANDA Submissions | 8/10/30 months | 80 | 74 | 3 | 0 | 3 | 0 | 100% | 12% to 100% | 100% | 12% to 100% |
| **II. Amendment Review** | | | | | | | | | | | |
| Standard Major ANDA Amendments | 8/10 months | 521 | 357 | 30 | 10 | 129 | 9 | 95% | 31% to 98% | 98% | 32% to 99% |
| Priority Major ANDA Amendments | 6/8/10 months | 88 | 48 | 12 | 2 | 26 | 0 | 100% | 47% to 100% | 100% | 47% to 100% |
| Standard and Priority Minor ANDA Amendments | 3 months | 746 | 262 | 227 | 80 | 178 | 68 | 86% | 58% to 91% | 98% | 64% 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, tentative approval, and CR actions.

## B. Performance Enhancement Goals Met

Table C-4 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 3001(b) of the Generic Drug User Fee Amendments of 2022 (i.e., the GDUFA III Commitment Letter) for the applicable fiscal year.

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

## Table C-4. FY 2025 Performance Enhancement Goals

| Performance Enhancement Goal | Target Goal Date | On Time (Y/N) | Actual Completion Date | Comments |
|---|---|---|---|---|
| **Pre-ANDA** | | | | |
| Update website information related to upcoming new and revised PSGs to support the development and approval of safe and effective generic drug products, including the projected date of PSG publication, which may be subject to change. | Quarterly | Y | Quarterly | https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development |
| Update the Inactive Ingredient Database on an ongoing basis and post quarterly notice of updates made. | Quarterly | Y | Quarterly | www.fda.gov/drugs/drug-approvals-and-databases/most-recent-changes-iid-database |
| Conduct a public workshop to solicit input from industry and stakeholders about the annual prioritization of PSGs and GDUFA III Regulatory Science Initiatives. | Annually | Y | Public Workshop held 6/03/2025–6/04/2025 | https://www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2025-generic-drug-science-and-research-initiatives-public-workshop-060320254 |
| 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 | Annually | https://www.fda.gov/drugs/generic-drugs/generic-drug-research-related-guidances-reports |
| Hold meetings between FDA and industry's GDUFA III regulatory science working group to collaborate on matters related to the GDUFA Science and Research Program, including the annual prioritization of PSGs and GDUFA III Regulatory Science Initiatives. | Biannually | Y | First Meeting held 10/30/2024<br><br>Second Meeting held 8/6/2025 | www.fda.gov/drugs/generic-drugs/generic-drugs-priorities-projects |
| **Facilities** | | | | |
| Update the Inspection Classification Database to reflect FDA's final assessment of the facility or site following an FDA inspection and assessment of the inspected entity's timely response to any documented observations. | Monthly | Y | Monthly | |
| **Continued Enhancement of User Fee Resource Management** | | | | |

| | | | | |
|---|---|---|---|---|
| Publish updates to the GDUFA Five-Year Financial Plan no later than the second quarter of each subsequent fiscal year. | Annually 3/31/2025 | N | 7/30/2025 | FDA published the GDUFA III Five-Year Financial Plan – 2025 Update in July 2025 (available at https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans). |
| Provide annual updates on FDA's website on the Agency's progress relative to activities detailed in the implementation plan that describes how resource capacity planning and time reporting will continue to be utilized during GDUFA III. | Annually 3/31/2025 | Y | 3/31/2025 | FDA published the Resource Capacity and Modernized Time Reporting Implementation Plan Annual Update in March 2025 (available at https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting). |
| Convene a public meeting no later than the third quarter of each fiscal year starting in FY 2024 to discuss the GDUFA Five-Year Financial Plan, along with the Agency's progress in implementing modernized time reporting and resource management planning. | Annually 6/30/2025 | N | 9/30/2025 | FDA held a public meeting on September 30, 2025 (see https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and). |
| Confirm progress in the hiring of GDUFA III staff in the GDUFA Five-Year Financial Plan. | Annually | Y | 7/30/2025 | See page 19 of GDUFA III Five-Year Financial Plan – 2025 Update (available at https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans). |
| **Performance Reporting** | | | | |
| Publish monthly reporting metrics set forth under section X(A) of the GDUFA III Commitment Letter. | Monthly | Y | Monthly | https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report |
| Publish quarterly reporting metrics set forth under section X(B) of the GDUFA III Commitment Letter. | Quarterly | Y | Quarterly | https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report |
| Publish fiscal year performance reporting metrics set forth under section X(C) of the GDUFA III Commitment Letter. | Annually | Y | Annually | See the Performance Reporting section of this FY 2025 GDUFA performance report |
| Post fiscal year reporting metrics on the web set forth under section X(D) of the GDUFA III Commitment Letter. | Annually | Y | Annually | https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-2024-fiscal-year-web-posting |
| Independent contractor completes and publishes an evaluation of the resource capacity planning capability by end of FY 2025 | 9/30/2025 | Y | 9/26/2025 | https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting |

## C. Common Causes and Trends Impacting Ability to Meet Goals

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

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

### Table C-5. FY 2023 GDUFA III Updated Performance Results

| Cause or Trend | Impact on FDA's Ability to Meet Goals |
|---|---|
| **Performance Goals** | In last year's report, the Agency could not fully report on this category because some submissions received in FY 2023 had associated review goals that fell within the subsequent fiscal year. The Agency has the following updates:<br>• "Standard Original ANDA Submissions" and "Priority Original ANDA Submissions": FDA met these goals. |

Table C-6 represents FDA's FY 2024 updated performance results.

### Table C-6. FY 2024 GDUFA III Updated Performance Results

| Cause or Trend | Impact on FDA's Ability to Meet Goals |
|---|---|
| **Performance Goals** | In last year's report, the Agency could not fully report on this category because some submissions received in FY 2024 had associated review goals that fell within the subsequent fiscal year. The Agency has the following updates:<br>• "Standard Original ANDA Submissions": Based on currently available data, FDA is meeting this goal. Some submissions have associated review goals that fall within next fiscal year. FDA will provide an update next year.<br>• FDA did not meet the FY 2024 performance goal "Priority Major ANDA Amendment". Many of the misses were concentrated around ANDAs for a single drug product. These ANDAs required extensive scientific review to resolve critical questions regarding active ingredient identification and characterization, creating cascading delays across review timelines. These issues have now been resolved.<br>• FDA met the remaining FY 2024 performance goals. |
| **Program Enhancement Goals and Other Goals** | In last year's report, the Agency could not fully report on this category because some submissions received in FY 2024 had associated program enhancement goals that fell within the subsequent fiscal year. The Agency has the following updates:<br>• FDA did not meet the FY 2024 program enhancement goal "FDA to provide a scheduled date for a requested Post-CRL teleconference." This was due to process changes related to this activity.<br>• FDA met the remaining FY 2024 program enhancement goals. |

Table C-7 represents FDA's FY 2025 preliminary performance results.

### Table C-7. FY 2025 GDUFA III Preliminary Performance Results

| Cause or Trend | Impact on FDA's Ability to Meet Goals |
|---|---|
| **Performance Goals** | Because some submissions received in FY 2025 have associated performance goals that fall within subsequent fiscal years (e.g., FY 2026), FDA cannot yet evaluate and report on the FY 2025 performance goals. FDA will provide an update next year. |
| **Program Enhancement and Other Goals** | Because some submissions received in FY 2025 have associated program enhancement goals that fall within subsequent fiscal years (e.g., FY 2026), FDA cannot yet evaluate and report on the FY 2025 program enhancement and other goals. FDA will provide an update next year. |

# Appendix D: FY 2025 Corrective Action Report

Under section 744C(c) of the FD&C Act, FDA is required to issue a corrective action report that details FDA's performance in meeting the review and performance enhancement goals identified in the letter described in section 3001(b) of GDUFA III (i.e., the GDUFA III Commitment Letter) for the applicable fiscal year.

If the Secretary of Health and Human Services determines, based on the analysis presented in the annual GDUFA performance report, that each of the review and performance enhancement goals for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the human drug application process.[1]

For any of the review and performance enhancement goals during the applicable fiscal year that were not met, the corrective action report shall include a justification, as applicable, for the types of circumstances and trends that contributed to missed review goal times; and with respect to performance enhancement goals that were not met, a description of the efforts FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year. Such a description of corrective efforts is not required by statute for review time goals, but FDA is nonetheless providing this information in an effort to be complete.

This section satisfies this reporting requirement.

## A. Executive Summary

### *1. FY 2023 Updated Performance Results*

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

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

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

| Goal Type | Circumstances and Trends Impacting the Ability to Meet the Goal Date | Corrective Action Plan |
|---|---|---|
| **Performance Goals** | Standard Original ANDA Submissions: FY 2023 goal met. | No corrective action plan is needed. |
| | Priority Original ANDA Submissions: FY 2023 goal met. | No corrective action plan is needed. |

## *2. FY 2024 Updated Performance Results*

Table D-2 represents FDA's FY 2024 updated performance results for goal types that the Agency was not able to fully report on in last year's report.

### Table D-2. FY 2024 GDUFA III Updated Performance Results for Goal Types Not Fully Reported Last Year

| Goal Type | Circumstances and Trends Impacting the Ability to Meet the Goal Date | Corrective Action Plan |
|---|---|---|
| **Performance Goals** | Standard Original ANDA Submissions: It is too soon to determine. | Based on currently available data, FDA is meeting this goal. Some submissions have associated review goals that fall within next fiscal year. FDA will provide an update next year. |
| | FDA did not meet the goal "Priority Major ANDA Amendment". Many of the misses were concentrated around ANDAs for a single drug product. These ANDAs required extensive scientific review to resolve critical questions regarding active ingredient identification and characterization, creating cascading delays across review timelines. These issues have now been resolved. | FDA has established a specialized scientific review team dedicated to identifying and addressing scientific issues during the early stages of the review process. This proactive approach is designed to:<br>• Provide early detection of applications requiring specialized scientific expertise<br>• Facilitate timely consultation and resolution of multifaceted technical questions<br>• Prevent late-stage delays that impact multiple goal dates<br>• Improve overall review efficiency and predictability |
| | All remaining FY 2024 goals were met. | No corrective action plan is needed. |
| **Program Enhancement Goals and Other Goals** | FDA did not meet the goal "FDA to provide a scheduled date for a requested Post-CRL teleconference." This was due to process changes related to this activity. | FDA has confirmed that written processes and training materials for Post-CRL teleconferences contain the grant/deny timeframes and has retrained staff involved in this process. |
| | All remaining FY 2024 goals were met. | No corrective action plan is needed. |

### *3. FY 2025 Performance Results*

Table D-3 represents FDA's FY 2025 preliminary performance results.

**Table D-3. FY 2025 Preliminary Performance Results**

| Goal Type | Circumstances and Trends Impacting the Ability to Meet the Goal Date | Corrective Action Plan |
|---|---|---|
| **Performance Goals** | It is too soon to determine. | Because some submissions received in FY 2025 have associated performance goals that fall within subsequent fiscal years (e.g., FY 2026), FDA cannot yet evaluate and report on the performance for FY 2025 performance goals. FDA will provide an evaluation next year. |
| **Program Enhancement and Other Goals** | It is too soon to determine. | Because some submissions received in FY 2025 have associated program enhancement goals that fall within subsequent fiscal years (e.g., FY 2026), FDA cannot yet evaluate and report on the performance for FY 2025 program enhancement and other goals. FDA will provide an evaluation next year. |
| **Performance Enhancement Goal: Pre-ANDA** | All FY 2025 goals met. | No corrective action plan is needed. |
| **Performance Enhancement Goal: Facilities** | All FY 2025 goals met. | No corrective action plan is needed. |
| **Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management** | FDA missed the goal to publish a GDUFA 5-year financial plan and the subsequent goal to hold a public meeting to present the financial plan. The financial plan, due by March 31, 2025, was published July 30, 2025. The public meeting, due by June 30, 2025, was held September 30, 2025. The delay in publishing the Five-Year Financial Plans reflects the Agency's commitment to providing accurate and meaningful financial projections. | FDA plans on meeting these commitments in FY 2026. |
| | All remaining FY 2025 goals met | No corrective action plan is needed. |
| **Performance Enhancement Goal: Performance Reporting** | All FY 2025 goals met. | No corrective action plan 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 2024 and 2025 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 2024 Performance Goal Performance*

**Summary of Performance**

FDA did not meet the goal “Priority Major ANDA Amendment.”

**Justification Regarding Missed Goals**

Many of the misses were concentrated around ANDAs for a single drug product. These ANDAs required extensive scientific review to resolve critical questions regarding active ingredient identification and characterization, creating cascading delays across review timelines. These issues have now been resolved.

**FY 2024 Corrective Actions**

FDA has established a specialized scientific review team dedicated to identifying and addressing scientific issues during the early stages of the review process. This proactive approach is designed to:
• Provide early detection of applications requiring specialized scientific expertise
• Facilitate timely consultation and resolution of multifaceted technical questions
• Prevent late-stage delays that impact multiple goal dates
• Improve overall review efficiency and predictability

**Summary of Performance**

Standard Original ANDA Submissions: Based on currently available data, FDA is meeting this goal. Because some submissions have associated review goals that fall within the next fiscal year, FDA will provide an evaluation in the FY 2026 report.

**Justification Regarding Missed Goals**

It is too soon to determine if a justification is needed.

**FY 2024 Corrective Actions**

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

### *2. FY 2025 Performance Goal Performance*

**Summary of Performance**

Because some submissions received in FY 2025 have associated performance goals that may fall within subsequent fiscal years (e.g., FY 2026), FDA cannot yet evaluate and report on the FY 2025 performance goals. FDA will provide an evaluation in the FY 2026 report.

**Justification Regarding Missed Goals**

It is too soon to determine if a justification is needed.

**FY 2025 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 2024 and FY 2025.

This section presents non-review performance enhancement goals cited in the GDUFA III Commitment Letter with specified completion dates in FYs 2024 and 2025. For the purposes of this report, "performance enhancement goals" are defined as any non-review performance goal with a specified deadline in the GDUFA III Commitment Letter.

### *1. FY 2024 Program Enhancement and Other Goals*

**Summary of Performance**

FDA did not meet the goal “FDA to provide a scheduled date for a requested Post-CRL teleconference.”

**Justification Regarding Missed Goals**

This missed goal was due to process changes related to this activity.

**FY 2024 Corrective Actions**

FDA has confirmed that written processes and training materials for Post-CRL teleconferences contain the grant/deny timeframes and has retrained staff involved in this process.

## *2. FY 2025 Program Enhancement and Other Goals*

**Summary of Performance**

Because some submissions received in FY 2025 have associated program enhancement goals that fall within subsequent fiscal years (e.g., FY 2026), FDA cannot yet evaluate and report on the FY 2025 program enhancement and other goals. FDA will provide an evaluation in the FY 2026 report.

**Justification Regarding Missed Goals**

It is too soon to determine if a justification is needed.

**FY 2025 Corrective Actions**

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

## *3. FY 2025 Performance Enhancement Goal: Pre-ANDA*

**Summary of Performance**

All FY 2025 goals were met.

**Justification Regarding Missed Goals**

No justification is needed.

**FY 2025 Corrective Actions**

No corrective action is needed.

### *4. FY 2025 Performance Enhancement Goal: Facilities*

**Summary of Performance**

All FY 2025 goals were met.

**Justification Regarding Missed Goals**

No justification is needed.

**FY 2025 Corrective Actions**

No corrective action is needed.

### *5. FY 2025 Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management*

**Summary of Performance**

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

**Justification Regarding Missed Goals**

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

**FY 2025 Corrective Actions**

FDA plans on meeting these commitments in FY 2026.

### *6. FY 2025 Performance Enhancement Goal: Performance Reporting*

**Summary of Performance**

All FY 2025 goals were met.

**Justification Regarding Missed Goals**

No justification is needed.

**FY 2025 Corrective Actions**

No corrective action is needed.

This report was prepared by FDA's Performance Management Staff in collaboration with FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research. For information on obtaining additional copies, please contact:

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