



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

Resource Capacity Planning and Modernized Time Reporting Implementation

Annual Update Fiscal Year 2026

MARCH 2026

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Purpose

The purpose of this annual update is to provide progress regarding the activities described in the March 2023 [Resource Capacity Planning and Modernized Time Reporting Implementation Plan](#).

The publication of this annual update satisfies the following commitments for fiscal year (FY) 2025:

- PDUFA VII: “FDA will provide annual updates on the FDA website on the Agency’s progress relative to activities detailed in (the March 2023) implementation plan by the end of the 2nd quarter of each subsequent fiscal year.”¹
- BsUFA III: “FDA will provide annual updates on the FDA website on the Agency’s progress relative to the activities detailed in (the March 2023) implementation plan on or before the end of the 2nd quarter of each subsequent fiscal year.”²
- GDUFA III: “FDA will provide annual updates on the FDA website on the Agency’s progress relative to activities detailed in (the March 2023) implementation plan by the end of the second quarter of each subsequent fiscal year.”³

An annual update will be published each subsequent fiscal year (FY) pursuant to the above commitments.

¹ PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027, p. 57 (<https://www.fda.gov/media/151712/download?attachment>)

² BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027, p. 32 (<https://www.fda.gov/media/152279/download?attachment>)

³ GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023 through 2027, p. 39 (<https://www.fda.gov/media/153631/download>)



Background

In FY 2018 (the first year of PDUFA VI, BsUFA II, and GDUFA II), FDA formally initiated efforts to establish a Resource Capacity Planning (RCP) capability to support these user fee programs. The idea for an RCP capability emerged from the user fee reauthorization process, and the commitment to establish this capability was memorialized in the respective commitment letters for these programs.

The intent of RCP is to build more systematic, data-driven, and repeatable processes to understand and anticipate current and future resource demand in these user fee programs, thereby enabling the Agency to proactively ensure its organizational components are optimally and efficiently resourced. FDA defined the following as a working vision statement to help guide the development of its RCP capability:

Develop a unified and trusted resource management capability to foster innovation and maximize our operational performance, facilitating a flow of products to patients first in the world in order to protect and promote public health and meet our commitments to the American public.

In addition to establishing RCP, FDA also committed to modernize its activity-based time reporting programs and to modernize the Capacity Planning Adjustment (CPA) methodology.

Recognizing the continued value of RCP to support optimal resourcing and operations, additional RCP-related commitments were agreed upon through the most recent user fee reauthorization process (covering FYs 2023–2027, accounting for PDUFA VII, BsUFA III, and GDUFA III). Those commitments included publishing a plan in FY 2023 describing how RCP and time reporting will continue to be implemented and utilized during PDUFA VII, BsUFA III, and GDUFA III.

FDA committed to provide annual updates on the Agency’s progress relative to the activities detailed in this implementation plan by the end of the second quarter of each subsequent fiscal year on the FDA website.

This document serves as the annual update for FY 2026. It describes progress to-date toward each item described in the implementation plan section of the March 2023 plan. Please reference section 3.2 of that plan.





Annual Update on Progress

The numbering in this section refers to the implementation plan section of the March 2023 plan.

3.2.1 Integrated Project Management, Portfolio Analytics, and Reporting Feasibility Assessment

In November 2024, FDA completed the feasibility study of integrated project management, portfolio analytics and reporting (phases 4 &5)⁴ with RCP. This study addressed the feasibility of this integration including an assessment of readiness, costs, pros, cons, gaps, and potential alternatives across the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research, and the Office of Inspections and Investigations (OII). FDA will continue evaluating the recommendations from the study and ensure continued coordination as appropriate across CBER, CDER, and OII.

3.2.2 RCP Updated Concept of Operations

FDA refined the existing RCP support and operating model in FY 2024. This operating model will be adapted annually as needed as part of a continual improvement process.

3.2.3 Continual Improvement of Time Reporting

As FDA rolled out the modernized time reporting, CDER, CDRH, CBER, and OII independently tailored, managed, and supported the Insight Time Reporting (ITR). FDA plans to unify the ITR by eliminating inconsistencies, standardize policies, maximize cross-functional support, streamline the user's experience, and enhance resource management across FDA's Resource Capacity Planning and Time Reporting program in FY 2026.

⁴See p. 13-14 of the [March 2023 implementation plan](#) for a description of phases 4 & 5

In FY 2025 OII continued to build on the successful implementation of ITR time reporting and pursued new initiatives to ensure continued compliance and reliable reporting across OII. Notable among these was an in-depth statistical analysis of 3-years of time reporting data. The study of nearly 9 million data points resulted in OII developing more accurate operational metrics used for work planning that better matched the different constraints and realities of our commodity-diversified and geographically dispersed inspectorates. As an added benefit, this exercise engaged management across OII and through it, all participants gained a deeper understanding and appreciation of how time reporting can be leveraged to improve OII's operational capacity to meet our mission.

3.2.4 Continual Improvement of the CPA

Enhancements and continual improvements of the CPA and related processes have continued, including in technical, analytical, and process areas.

FDA continues to utilize and enhance the cloud-based technology platform to support RCP work with a more effective modeling capability with increased efficiency.

FDA migrated CBER and CDER CPA resource forecasting codes or scripts to the cloud-based technology platform and conducted extensive user acceptance testing to ensure the accuracy of CPA model outputs. The enhancements will streamline and increase efficiencies within the CPA refresh process.

3.2.5 Integrating RCP Analyses into Financial and Operational Decision-Making Processes

RCP continues to engage in efforts to provide analytic support to further the efficiency and effectiveness of regulatory operations in CBER, CDER, and OII as appropriate. In addition, work has continued to harden processes connecting time reporting data to financial management on FDA programs. This includes processes to align time reporting data to inform relevant tables required for FDA's budget justification documents.

3.2.6 The Implementation of the GDUFA CPA

CDER is making continual improvements of the GDUFA CPA. CDER has modified the GDUFA CPA resource forecasting model to subdivide:

- The ANDA supplements forecast into Prior Approval Supplements (PAS) and Changes Being Effected (CBE) categories for the FY 2026 GDUFA CPA;
- The ANDA original forecast into ANDA complex and ANDA non-complex categories for the FY 2027 GDUFA CPA.



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