Evaluation of FDA Resource Capacity Planning for PDUFA, BsUFA and GDUFA

Final Report

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Executive Summary

Before the 1990s, the U.S. Food and Drug Administration (FDA) sometimes lacked sufficient resources to perform medical product review activities in a timely manner. To address this issue, Congress enacted a series of User Fee Acts (UFAs) to authorize FDA to collect user fees from medical product sponsors; these include the Prescription Drug User Fee Act (PDUFA) in 1992 and the Biosimilar User Fee Act (BsUFA) and Generic Drug User Fee Act (GDUFA) in 2012. Each UFA is reauthorized every five years and statutorily defines the types of fees that FDA may collect—and the types of work that FDA may use to determine what the fees should be. These fees, plus congressional appropriations, provide funding for timely work on medical product development programs and applications.

Since the initial enactment of the UFAs, workload for medical product reviews has increased each year. As a result, the initial total revenue amount for each UFA was no longer sufficient to cover FDA's review costs. To address this issue, for PDUFA III (FY2003) industry and FDA agreed on a methodology to calculate how much the total revenue amount should change each year. This methodology has evolved over the years. For PDUFA VI, BsUFA II, and GDUFA II, FDA committed to modernizing its time reporting systems, establishing a resource capacity planning (RCP) capability, and implementing a new method of forecasting UFA resource needs. The new method is called the Capacity Planning Adjustment (CPA) methodology.

For PDUFA VII, BsUFA III, and GDUFA III, FDA also committed to hire an independent contractor to evaluate FDA's RCP capability. FDA enlisted Eastern Research Group, Inc. (ERG) to conduct the evaluation. As stipulated in the commitment letter for each UFA, the evaluation must assess the following:

1. The ability of the CPA to forecast resource needs for the PDUFA, BsUFA, and GDUFA programs, including an assessment of the scope of the workload drivers in the CPA and their ability to represent the overall workload of the PDUFA, BsUFA, and GDUFA programs.
2. Opportunities for the enhancement of time reporting toward informing resource needs.
3. The integration and utilization of resource capacity planning information within resource and operational decision-making processes of the PDUFA, BsUFA, and GDUFA programs.

ERG began by developing a set of assessment questions to address the three evaluation objectives. Next, we defined the metrics needed to answer the assessment questions--and prepared data collection protocols and instruments to collect data from FDA databases, documents, and staff interviews. These data encompass FY2021 to FY2025. We then analyzed the data to generate results for the metrics and gain insights into what is working well and what could be improved. Finally, we developed answers to the assessment questions and distilled results into findings and recommendations.

Answers to Evaluation Questions

Below are high-level summaries of ERG's answers to the assessment questions, organized by evaluation objective.

Evaluation Objective #1: Evaluate CPA Methodology's Ability to Forecast Resource Needs for PDUFA, BsUFA, and GDUFA Programs:

1. **To what extent has the CPA approximated actual changes in FDA workload for the PDUFA/BsUFA/GDUFA program from inception of the CPA to present?** To date, FDA's CPA methodology has produced resource forecasts—as measured by full-time equivalents (FTEs) adjusted for internal support—that fall within 10 percent of actual values. This has been true every year since the CPA's inception for PDUFA (FY2021-present), BsUFA (FY2021-present), and GDUFA (FY2024-present). Moreover, the CPA methodology achieved "Very High" or "High" ratings for all nine evaluation metrics. As a result, we conclude that the CPA accurately forecasts changes in FDA workload for PDUFA, BsUFA, and GDUFA.

2. **To what extent have the workload drivers in the CPA methodology represented actual UFA program work from inception of the CPA to present?** The workload drivers in the CPA methodology (a set of submission categories statutorily allowed to be included in the calculation) are a reasonably good representation of overall workload for each UFA. For each UFA, the workload drivers represent a reasonably consistent percentage of overall UFA work, fluctuating by 4 percent or less each year.

3. **In what ways might workload drivers change in upcoming PDUFA/BsUFA/GDUFA years, and how might those changes impact CPA performance?** To date, the CPA methodology has been flexible enough to accommodate the addition of new workload drivers as well as new account codes in the time reporting system. The methodology is sufficiently flexible to accommodate additional changes that could occur in the future. For example, the methodology can accommodate:

    - Changes in the relative volume of different types of submissions and other allowable work activities.
    - Addition (or deletion) of workload drivers, if necessary. FDA might need to develop new models to accommodate new drivers, but the methodology provides a structural and conceptual foundation for doing so.
    - New account codes in FDA's time reporting system, if needed to accommodate changes in drivers.
    - Unforeseen changes in submission volume or average review staff salary (e.g., if the volume of submissions requiring higher paid expert increases) by means of the managerial adjustment. To date, FDA has not needed to use the managerial adjustment to address these types of changes, but could do so if necessary.

Evaluation Objective #2: Evaluate Opportunities to Enhance Time Reporting

4. **What (if any) changes to FDA's time reporting system or practices would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts?** FDA has modernized its time reporting system to improve accuracy in reporting and resource forecasting for PDUFA, BsUFA, and GDUFA. ERG's evaluation demonstrates that the CPA methodology generates accurate resource forecasts using data from the time reporting system. Daily time entry, which FDA encourages but does not require, might produce incremental improvements in the accuracy of resource forecasts. Private industry generally considers

daily time entry to be a best practice. This could be burdensome for some FDA staff, however. FDA can encourage daily time reporting when it adds value but allow for flexibility when it is not practical.

Evaluation Objective #3: Evaluate Integration and Use of RCP Information in Resource and Operational Decision-Making

5. **How does FDA use its RCP capability for other PDUFA/BsUFA/GDUFA resource and operational decision-making processes?** For other PDUFA, BsUFA, and GDUFA resource and operational decision-making processes beyond calculating the CPA for user fee setting, FDA uses its RCP capability to:

   - Quantify resource utilization and forecast resource needs in specific offices and divisions based on past, present, and future trends and fluctuations in workload. For example, RCP staff produce analyses of time reporting data that offices and divisions use for resource planning. RCP staff also develop models to facilitate resource allocation and forecasting and determine how to shift workload across offices/divisions to optimize operations.
   - Guide financial operations. For example, FDA calculates process cost percentages (percentages of total cost that UFA processes represent) to support UFA budgeting, implementation, and overall financial management.

6. **What (if any) changes to FDA's RCP capability would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts and related operational decision-making processes?** FDA could make two changes:

   - Replicate models to improve resource and operational decisions for other super offices and offices. This could help other offices understand resource allocation processes and make decisions based on the same principles. Continuing to work with office leaders/staff will facilitate ongoing improvements to existing models and replicability of additional models.
   - Continue to provide FDA technology teams responsible for OneNexus and CDEROne with current and future requirements to enable RCP staff to perform their duties as efficiently as possible. OneNexus is a workflow platform and has the potential to manage time reporting and the majority of regulatory processes through a single, integrated interface. RCP staff can benefit from this platform by having centralized access to many more data sources for modeling efforts. CDEROne is an analytics platform that uses cloud technologies and provides a single point of access for a conglomeration of analytics solutions to support CDER business needs. By streamlining data preparation and increasing the speed of data processing, CDEROne facilitates more efficient model testing and development of data insights (including workload forecasts) by RCP staff.

7. **What (if any) changes to FDA's RCP capability would improve its utility for other operational decision-making processes?** FDA's UFA financial planning processes are strong methodologically, well established, consistently applied, and widely considered accurate. ERG does not recommend additional changes.

Findings and Recommendations

Based on our evaluation, ERG developed the following findings and recommendations.

Table ES-1. Findings and Recommendations

Number	Finding	Recommendation(s)
Overarching		
O1	Overall, the CPA methodology performs well in forecasting workload and resource needs. The workload drivers are a reasonably good representation of overall workload for each UFA.	No action needed.
O2	FDA maintains complete, thorough, and accurate documentation of the CPA methodology. The agency also maintains a complete repository of data used as inputs, CPA methodology results, analyses of CPA performance, and updates to the CPA methodology. Further organizing and streamlining CPA methodology documentation could benefit RCP staff (especially those new to the CPA methodology).	Further organize and streamline internal documentation of the CPA methodology by: • Consolidating and standardizing the format of the documents. • Adding visual aids to show relationships to steps in the CPA methodology. • Standardizing and defining terms. • Adding version numbers and dates to track updates.
O3	The time reporting system is easy to use, flexible, and provides accurate time reporting data. FDA currently encourages daily time reporting and requires staff to record their hours at the end of each two-week tour of duty (TOD).	Continue to encourage daily time reporting to potentially further improve the accuracy and reliability of time reporting data, but allow for flexibility for FDA staff for whom this too burdensome due to their role. FDA could explore sending daily reminders to staff, close to the end of the business day.
O4	RCP use for financial planning is well-established and functioning well.	No action needed.
05	FDA's RCP capability is well positioned to meet future needs for resource and operational decision-making. RCP staff are strategic in anticipating needs and how to best meet them. For example, FDA is: • Expanding use of RCP for resource and operational decision-making. Reports and data-driven models are useful, with minor recommendations for improvements. • Working on developing analytical models and simulation approaches to test opportunities for more efficient and effective regulatory operations, such as managing industry meetings. • Providing FDA technology teams with needs and suggestions to facilitate	Incorporate the minor improvements recommended to resource forecasting models suggested by users. Determine how similar resource forecasting models might be incorporated elsewhere in FDA (e.g., CDER or CBER offices that do not currently utilize these models) for operational and resource-decision making. Continue RCP modernization initiatives, including analytical models and simulation approaches and migrating processes and data to the CDEROne and OneNexus environments.

Number	Finding	Recommendation(s)
	building a centralized CDER analytical environment that enables faster data processing and use of more models for RCP-related work. CBER will undertake a similar initiative. An effort to migrate to a centralized workflow management platform is also in development.	
UFA-Specific		
S1	For PDUFA, CBER is working on maturing its RCP capability (similar to efforts implemented by CDER).	No action needed. CBER is already working to mature its RCP capability.
S2	The CPA methodology performs well for all three UFAs. The CPA methodology for BsUFA tends to under forecast BsUFA workload, but this is due to the small volume of submissions and the lack of historical data when FDA developed the initial submission forecast models rather than any flaw in the methodology.	Now that FDA has some years of historical data, revisit the BsUFA models and methodologies.

1. Introduction

The mission of the Food and Drug Administration (FDA) is to protect and advance public health—in part by helping to speed innovation and ensuring the safety and effectiveness of medical products. To that end, FDA provides advice to medical product sponsors during development, reviews applications to market new medical products, and monitors the availability and safety of approved products on the market. Before the 1990s, FDA sometimes lacked sufficient resources to perform these activities in a timely manner. To address this issue, Congress enacted a series of User Fee Acts (UFAs) to authorize FDA to collect user fees from medical product sponsors. These fees, plus congressional appropriations, provide funding for timely work on medical product development programs and applications. In return, FDA commits to timeliness performance targets.

Congress initially authorized each UFA for a 5-year period. Every 5 years, it reauthorizes each UFA for another 5-year period. For each UFA, the statute defines the types of fees that FDA may collect, describes the process for establishing the user fee revenue amount for each year, and lists the types of work that FDA may use to determine the user fee revenue amount. An FDA commitment letter lists agency review goals for the duration of the UFA.

At the inception of each UFA program, FDA negotiated a fee structure with industry. As review workload increased each year, the initial total revenue amount stated in statute was no longer sufficient to cover FDA's costs. To address this issue, industry and FDA agreed on a methodology to calculate how much the total revenue amount should change each year. This report addresses FDA's approach to calculating adjustments to total user fee revenue amounts to account for resource needs for three UFA programs (Table 1-1). The remainder of this introduction covers three topics:

- Section 1.1 History of PDUFA, BsUFA, and GDUFA Workload Estimation
- Section 1.2 Purpose of this Evaluation
- Section 1.3 This Report

Table 1-1. UFAs Addressed in This Report

UFA	Current Authorization	Medical Products Covered	FDA Centers/Offices that Perform UFA Program Work Included in the User Fee Adjustments to Account for Resource Needs
Prescription Drug User Fee Act (PDUFA)	PDUFA VII (Fiscal Year (FY) 2023-FY2027)	New drugs (including biologics)	Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) Center for Devices and Radiological Health (CDRH) Office of Inspections and Investigations (OII) FDA Headquarters (HQ)

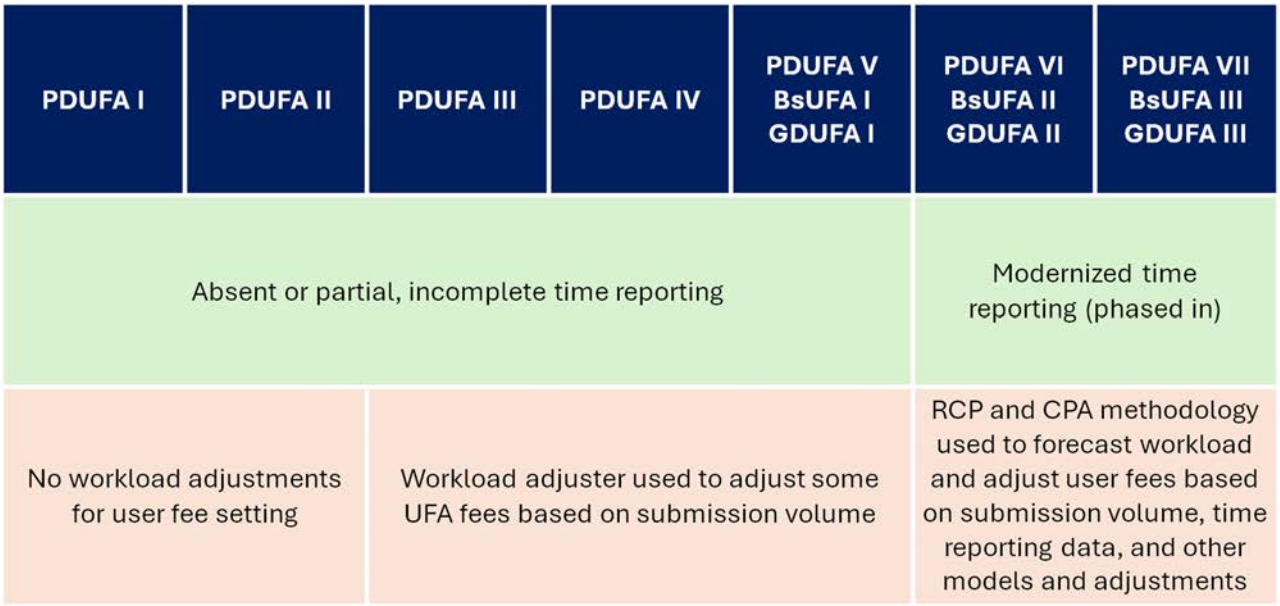
Biosimilar User Fee Act (BsUFA)	BsUFA III (FY2023-FY2027)	Biosimilar biological products	CDER CBER OII HQ
Generic Drug User Fee Act (GDUFA)	GDUFA III (FY2023-FY2027)	Generic drugs	CDER CBER OII HQ

1.1 History of PDUFA, BsUFA, and GDUFA Workload Estimation

Estimation of Workload in PDUFA I-V

Congress first enacted PDUFA in 1992. For the first two authorizations (PDUFA I and PDUFA II), the statute did not provide a process for FDA to adjust the user fee revenue amount each year to account for changes in expected workload. For PDUFA III, industry and FDA agreed on a methodology (described in the statute). Accordingly, FDA implemented the PDUFA Workload Adjuster to estimate a percent change in workload resulting from an increased volume of submissions to review (Figure 1-1). FDA used this estimated percent change to adjust the total amount of revenues from PDUFA user fees each year.

Figure 1-1. History of FDA's PDUFA, BsUFA, and GDUFA Workload Estimation



As originally implemented, the PDUFA Workload Adjuster estimated changes in workload based on historical numbers of submissions for each type statutorily allowed to be used in estimating workload:

- Calculate the percent change in a rolling average number of submissions.
- Multiply the percent change by a weighting factor to account for the total work that the submission category represents.

- Sum the weighted percent changes (for all submission categories) to estimate total percent change in workload.

In 2007, for PDUFA IV, FDA changed the measurement of certain submissions and added a complexity factor to account for changes in the *complexity* of reviews in addition to the *volume* of reviews. FDA calculated the complexity factor based on counts of five activities in reviews of Investigational New Drug (IND) submissions and applications to market new drugs and biologics. In PDUFA V, FDA removed the complexity factor because it did not work as intended.

Estimation of Workload in PDUFA VI-VII, BsUFA II-III, and GDUFA II-III

Though useful for its initial purpose, the PDUFA Workload Adjuster had several flaws that made it less than optimal for estimating human drug review workload over time. For example, it did not encompass all drivers of human drug review workload, used lagging indicators to estimate submission volume for an upcoming year rather than leading indicators to predict future workload, relied on submission volumes rather than actual hours worked, produced a percentage to use to adjust total PDUFA revenue amount rather than estimates of hours or FTEs needed to perform future work, and lacked mechanisms to assess the reasonableness of its output. During our 2015 assessment of the Workload Adjuster, ERG and FDA discussed these flaws—and the need for a modernized time reporting system[1] to produce some of the data needed to address these flaws.

For PDUFA VI, BsUFA II, and GDUFA II, FDA committed to modernizing its time reporting systems (which it did between 2018 and 2021) and establishing a RCP capability (which it did in 2020). These initiatives created the foundation for a new method of forecasting resource needs and adjusting total user fee revenue amounts for expected workload for PDUFA, BsUFA, and GDUFA: the CPA methodology. The goal of the CPA methodology is to more accurately forecast resource needs based on actual time reporting data and workload forecast modeling—to help overcome the flaws in the Workload Adjuster that made it an imprecise, backward-looking tool. In FY2018, statute directed FDA to use an interim CPA methodology to replace the Workload Adjuster for PDUFA. FDA used the interim CPA methodology from FY2018 to FY2020—until a more robust CPA methodology was ready for implementation in FY2021.

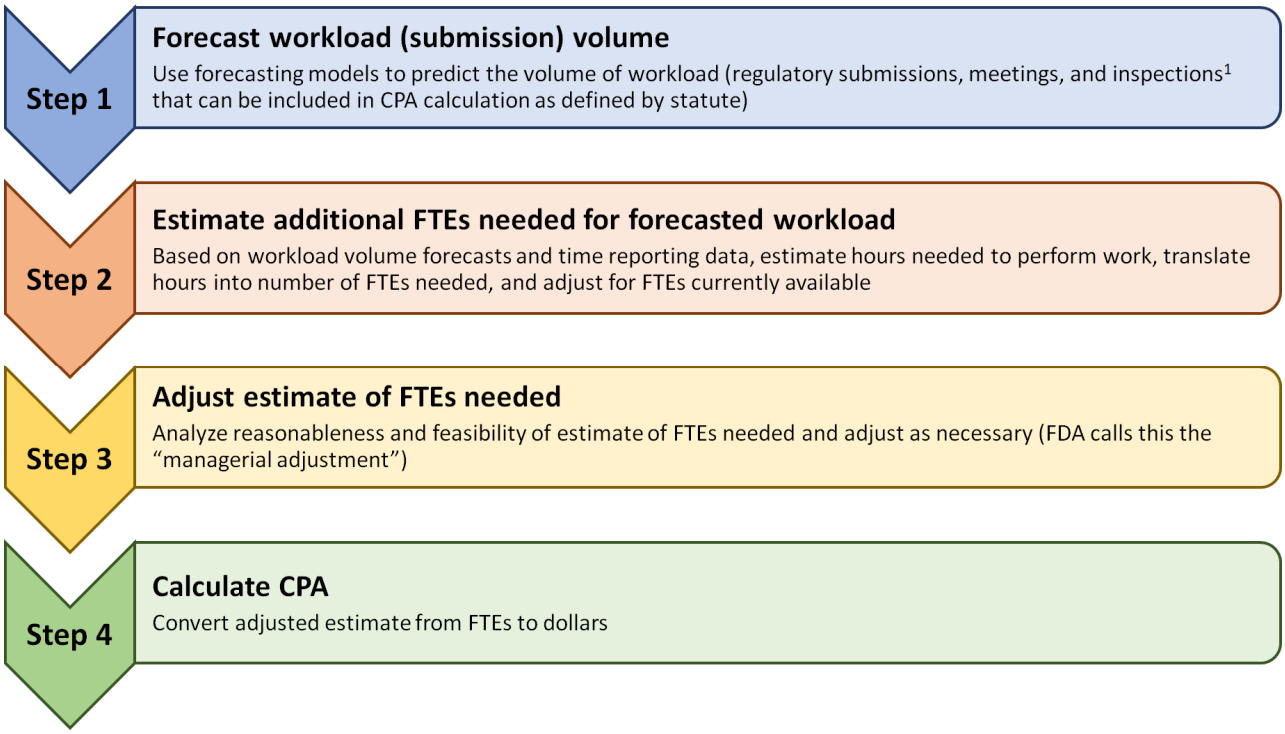
CPA Methodology

The CPA methodology involves four main steps to calculate the CPA—the amount by which FDA should adjust total user fee revenue amount for expected workload—to have sufficient resources to cover the forecasted workload for a given UFA (Figure **1**-2). After initial independent evaluations[2,3] found that the CPA methodology is an improvement from the Workload Adjuster and accurately assesses changes in the

[1] Modernized time reporting entails moving from sampling to year-round reporting, coupled with enhanced tools, processes, and support models to generate better data for workload estimation and operational decision-making.
[2] Booz Allen Hamilton. *Independent Evaluation of the PDUFA and BsUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations*. *https://www.fda.gov/media/136606/download*
[3] Booz Allen Hamilton. *Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations*. *https://fda.report/media/140656/Independent+Evaluation+of+the+GDUFA+Resource+Capacity+Planning+Adjustment+Methodology_0.pdf*

UFA program resource needs, UFA statutes authorized FDA to implement the methodology starting in FY2021 (PDUFA and BsUFA) and FY2024 (GDUFA). For each UFA, FDA uses a CPA methodology for each center/office that performs work that statute allows to be included in the CPA; for GDUFA, FDA has implemented the CPA methodology for CDER and has not yet implemented the methodology for OII. Each year, FDA analyzes results and makes improvements to the CPA methodology. Please see Section 3 for a more detailed explanation of the current CPA methodology and Appendix B for more information about improvements that FDA has made over time.

Figure 1-2. FDA's CPA Methodology Steps



[1] Only the OII GDUFA CPA methodology includes inspections.

1.2 Purpose of this Evaluation

For PDUFA VII, BsUFA III, and GDUFA III, FDA committed to hire an independent contractor to evaluate FDA's CPA methodology—and its RCP capability more broadly. FDA enlisted ERG to conduct the evaluation. The three main objectives are to evaluate:

- The ability of the CPA to forecast resource needs for the PDUFA, BsUFA, and GDUFA programs, including an assessment of the scope of the workload drivers in the CPA and their ability to represent the overall workload of the PDUFA, BsUFA, and GDUFA programs.
- Opportunities for the enhancement of time reporting toward informing resource needs.
- The integration and utilization of resource capacity planning information within resource and operational decision-making processes of the PDUFA, BsUFA, and GDUFA programs.

ERG translated these objectives into a set of questions to be answered by the evaluation (see text box).

Program Evaluation Questions

1. To what extent has the CPA approximated actual changes in FDA workload for the PDUFA/BsUFA/GDUFA program from inception of the CPA to present?
2. To what extent have the workload drivers in the CPA methodology represented the actual work of these UFA programs from inception of the CPA to present?
3. In what ways might workload drivers change in upcoming PDUFA/BsUFA/GDUFA years, and how might those changes impact CPA performance?
4. What (if any) changes to FDA's time reporting system or practices would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts?
5. How does FDA use its RCP capability for other PDUFA/BsUFA/GDUFA resource and operational decision-making processes?
6. What (if any) changes to FDA's RCP capability would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts and other related operational decision-making processes?
7. What (if any) changes to FDA's RCP capability would improve its utility for other operational decision-making processes?

1.3 This Report

This report presents findings from ERG's evaluation of FDA's CPA methodology and other RCP capability for PDUFA, BsUFA, and GDUFA; because FDA has not yet implemented the GDUFA CPA methodology for OII, we discuss it separately (Appendix C). The remainder of this report includes:

- Section 2: Methods
- Section 3: CPA Methodology
- Section 4: Assessment Questions and Answers
- Section 5: Findings and Recommendations
- Appendix A: Acronyms
- Appendix B: Results Supporting Evaluation
- Appendix C: OII GDUFA CPA Methodology Evaluation Results
- Appendix D: Text Description of Figures

2. Methods

ERG used a systematic process to identify, collect, and analyze comprehensive data for the evaluation of FDA's RCP capabilities. This process involved four key steps:

- Develop evaluation metrics, protocols, and instruments
- Collect data
- Analyze data
- Develop findings and recommendations

ERG collected data separately for PDUFA, BsUFA and GDUFA. The time bounds of our evaluation are FY2021 through FY2025.

2.1 Develop Evaluation Metrics, Protocols, and Instruments

ERG began by developing an evaluation framework consisting of the assessment questions we need to answer to meet the evaluation objectives and the metrics we need to measure to answer the assessment questions (Table 2-1).

The evaluation metrics establish a structure for data that need to be collected to generate results. Accordingly, ERG prepared protocols and instruments for collecting needed data. In general, ERG collected data by interviewing FDA staff, obtaining data from FDA databases, and examining documentation.

ERG developed four evaluation workbooks in Excel: one each for PDUFA, BsUFA, and GDUFA and one overarching workbook (Figure 2-1). ERG used the UFA-specific workbooks to store and analyze UFA-specific data (in separate worksheets, by metric). We used the overarching workbook to store data that apply to all UFA programs as well as high-level results of UFA-specific analyses.

Figure 2-1. Evaluation Workbooks

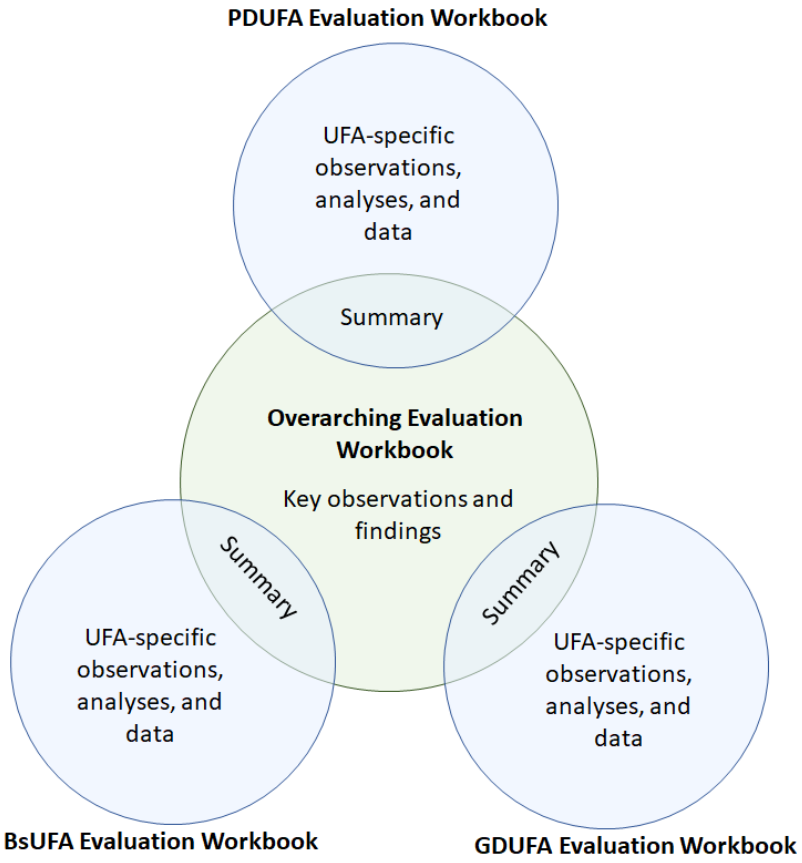


Table 2-1. Evaluation Framework

Evaluation Objective	Evaluation Questions	Evaluation Metrics
1. Evaluate the ability of the CPA methodology to forecast resource needs for PDUFA, BsUFA, and GDUFA, including an assessment of the scope of the workload drivers in the CPA and their ability to represent the overall workload of the PDUFA, BsUFA, and GDUFA programs.	1. To what extent has the CPA approximated actual changes in FDA workload for the PDUFA/BsUFA/GDUFA program from inception of the CPA to present? 2. To what extent have the workload drivers in the CPA methodology represented the actual work of these UFA programs from inception of the CPA to present? 3. In what ways might workload drivers change in upcoming PDUFA/BsUFA/GDUFA years, and how might those changes impact CPA performance?	For each UFA program: • CPA accuracy (percent difference between forecasted and actual resource needs) • CPA breadth (percent match between CPA workload drivers and actual workload over time) • CPA defensibility (rating that reflects whether assumptions on which CPA is based can reasonably be expected to be valid) • CPA feasibility (rating that reflects whether CPA works with existing tools and resources) • CPA stability (rating that reflects whether CPA represents changes in workload without overrepresenting or underrepresenting volatility) • CPA predictability (rating that reflects whether CPA provides adjustments that FDA and industry can reasonably anticipate; for FDA, that means providing sufficient lead time to permit timely hiring for workload funded by user fee adjustments) • CPA straightforwardness (rating that reflects whether CPA is based on a reasonably simple methodology, without relying on excessively complex statistical models or excessive data fields, variables, or components) • CPA transparency (rating that reflects whether CPA has explicit, clearly documented methodologies, assumptions, rationales, data sources, and calculations) • CPA flexibility (rating based on adaptability to encompass future changes in workload drivers)
2. Evaluate opportunities for the enhancement of time reporting toward informing resource needs.	4. What (if any) changes to FDA's time reporting system or practices would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts?	For each UFA program: • Strengths of FDA's time reporting system and practices for the CPA/RCP • Weaknesses of FDA's time reporting system and practices for the CPA/RCP
3. Evaluate the integration and utilization of resource capacity planning	5. How does FDA use its RCP capability for other PDUFA/BsUFA/GDUFA	For each UFA program: • List of uses of RCP for resource and operational decision-making processes • Strengths of FDA's RCP capability for resource forecasts

Evaluation Objective	Evaluation Questions	Evaluation Metrics
information in resource and operational decision-making processes for the PDUFA, BsUFA, and GDUFA programs.	resource and operational decision-making processes? 6. What (if any) changes to FDA's RCP capability would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts and related operational decision-making processes? 7. What (if any) changes to FDA's RCP capability would improve its utility for other operational decision-making processes?	• Strengths of RCP for each use • Opportunities for improvement of FDA's RCP capability for resource forecasts • Opportunities for improvement of RCP for each use

2.2 Collect Data

ERG collected all data, both qualitative and quantitative, in accordance with the procedures specified in our protocols and instruments. For PDUFA and BsUFA, ERG collected all data available for FY2021 to FY2025. For GDUFA, ERG collected data for FY2024 to FY2025 (because FDA began implementing the GDUFA CPA methodology in FY2024).

In addition to collecting data and documentation on the CPA methodology, time reporting, and other RCP capabilities, ERG interviewed FDA's RCP staff and FDA staff who use RCP outputs to generate additional insights and data for our evaluation. ERG entered raw data into each workbook, using separate worksheets for each metric.

2.3 Analyze Data

ERG used the evaluation workbooks to categorize and systematically organize data by metric for PDUFA, BsUFA, and GDUFA. We then analyzed the data to answer the assessment questions:

- Qualitative analysis to gain insights into RCP capabilities (including the CPA methodology and time reporting systems) and develop the qualitative evaluation metrics.

  ERG collected and organized documentation, including methodologies, procedures, reports, presentations, structured analyses, data outputs, and notes from interviews with FDA staff as inputs to the evaluation. We explored these data to gain an understanding of methodologies, identify strengths and weaknesses of methodologies, systems, and capabilities, and provide results for our metrics.

- Quantitative analysis to calculate metrics, especially for the first four assessment questions.

  ERG collected and organized data, including number of annual submissions, results for each step in the CPA methodology, and time reporting data as inputs to the evaluation. We explored the data to calculate metrics for CPA methodology accuracy and breadth as well as strength and weakness of time reporting systems.

2.4 Develop Findings and Recommendations

Based on the analyses described above, ERG developed cohesive, integrated answers to the assessment questions. ERG then distilled all results into a set of findings and recommendations.

3. CPA Methodology

The CPA is an adjustment applied to total UFA revenue amount to account for resources required for sustained increases in review workload in an upcoming year. The CPA methodology is a standardized, data-driven approach to calculate the CPA for each UFA. FDA calculates a CPA by center/office:

- PDUFA CPA = PDUFA CPA for CDER + PDUFA CPA for CBER
- BsUFA CPA = BsUFA CPA for CDER
- GDUFA CPA = GDUFA CPA for CDER + GDUFA CPA for OII[4]

3.1 Terms Used in CPA Methodology

Table 3-1 provides definitions of terms used in the CPA methodology, organized by step in the process. UFA statutes dictate the types of work that are "in scope" (i.e., that FDA may include) in the CPA:

- **In scope:** Direct review work and internal support for direct review work (see Table 3-2 for lists of categories of in-scope work by UFA).
- **Not in scope:** Indirect review work.

Table 3-1. Terms Used in CPA Methodology, by Step in the Process

Term	Definition
Step 1. Forecast workload (submission) volume	
Super office	Larger organizational unit with multiple offices that handle specific functions. Some offices do not belong to a super office. The CPA methodology generates workload and resource forecasts at the office level; when offices belong to a super office, FDA sums office-specific values to the super office level. *Note: In CBER, only the Office of Therapeutics is officially a super office. For CPA forecasting purposes, FDA (and ERG) treat all CBER offices as super offices.*
Direct review work	Work directly related to a drug review and statutorily permitted to be included in the CPA methodology (e.g., New Drug Application (NDA)/Biologics License Application (BLA) original submission review, industry meeting).
Direct effort category (also called workload driver)	Category of direct review work; collectively, all the direct effort categories sum to total direct review work.

[4] FDA has not yet implemented the OII GDUFA CPA methodology. As a result, the GDUFA CPA currently includes only the CDER GDUFA CPA. In the body of this report, ERG reviews the CPA methodology for PDUFA (CBER and CDER), BsUFA (CDER), and GDUFA (CDER only). We review the OII GDUFA CPA methodology separately (Appendix C).

Term	Definition
Indirect review work	Work that supports review and other regulatory work related to an UFA program but not related to a specific submission (e.g., guidance and policy work). FDA does not include this work in the CPA methodology.
Submission	Unit of work that is in scope for the CPA methodology (e.g., an individual PDUFA NDA submission, an individual industry meeting).
Workload forecast	Forecast of direct review workload volume by direct effort category. The CPA methodology uses predictive models to generate these forecasts.
Step 2. Estimate additional FTEs needed for forecasted workload volume (FTE delta)	
Unit effort	Average number of hours spent by FDA staff to complete review of one submission. The CPA methodology calculates this as total hours spent on a direct effort category divided by total submission volume for that category (average of the last three fiscal years).
Algorithm engine	FDA tool that uses the workload forecast (from Step 1) and unit effort to estimate additional resources required to meet anticipated submission workload (in hours) for an UFA program.
Full-time equivalent (FTE)	Unit of measure for the amount of work a full-time position performs. For the purpose of the CPA methodology, FDA defines an FTE as 2,080 hours per year. In the methodology, FDA calculates the number of FTEs needed to perform the amount of work projected for the upcoming year. Using FTEs (instead of number of employees) accounts for differences in staff schedules (part time, full time, more than full time).
Resource forecast	Number of FTEs necessary to support forecasted direct review workload volume.
Internal support work	Work related to the lifecycle of an employee in an UFA program (e.g., training, professional development, leave, and administrative activities), but not part of direct or indirect review work. A proportion of internal support for direct review work is in scope for the CPA methodology.
FTEs adjusted for internal support	Number of FTEs needed to support the forecasted workload volume or currently available to support workload volume at the center level to account for internal support work related to direct review work.
FTE delta	Difference between the number FTEs needed to support the forecasted workload volume (adjusted for internal support) and the current review capacity adjusted for internal support.
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)	
Managerial adjustment	Process applied to the FTE delta to reflect additional factors to ensure that the resource forecast is reasonable and feasible.
Adjusted FTE delta	Output of the managerial adjustment: FTE delta adjusted for additional factors.
Net gains cap	The maximum FTEs that can be hired at the center/office level per fiscal year. It is calculated by examining the net FTE gains per year for five years

Term	Definition
	of historical data hiring data and selecting the maximum net gain in those five years.
Step 4. Calculate CPA	
CPA	Final output of the CPA methodology. The CPA is calculated by multiplying the adjusted FTE delta by the center-specific full cost of one FTE.

3.2 Steps in CPA Methodology

Step 1. Forecast workload (submission) volume

The first step in the CPA methodology uses predictive models to forecast the volume of work for each direct effort submission category for the UFA for the next fiscal year. Doing so involves several steps (Figure 3-1). To perform the calculations, the methodology uses statistical programming software on the CDEROne platform.

Step 2. Estimate number of additional FTEs needed to perform forecasted volume of work (FTE delta)

The second step in the CPA methodology is to estimate the number of additional FTEs needed to perform the forecasted volume of work from Step 1. FDA uses a program called the "algorithm engine" for this purpose. The algorithm engine consists of statistical programming software that uses workload forecasts from Step 1 and time reporting data to perform the calculations. As shown in Figure 3-2, the algorithm engine calculates the following values:

- Number of FTEs needed to perform forecasted workload volume: based on forecasted volume of submissions and estimates of unit effort (time needed per submission), converts forecasted hours of work to the number of FTEs needed to perform the forecasted workload.

Technical Environment

CDEROne is a data analytics platform that houses many CDER data systems and tools—and stores, ingests, processes, and publishes data. CDEROne also houses tools and systems for CBER, including CBERWon. CDEROne uses Databricks to process data across sources. FDA's RCP team is working with FDA technology teams to move most parts of the CPA methodology to CDEROne, which will provide a more efficient computing environment. CDER's workload forecasting models and time reporting data are on CDEROne; FDA is working to move other components (e.g., the algorithm engine) as well.

Granularity of Calculations

In the CPA methodology, calculations (such as forecasted workload volume, unit effort, direct hours, forecasted FTEs, current capacity FTEs, FTE deltas, and adjusted FTE deltas) occur at the most granular level possible: the super office or office level. For CBER, the methodology forecasts workload volume at the product level—and then maps results to the CBER office where the work originated. For each UFA, the adjusted FTE delta is the sum of the adjusted FTE deltas for each super office/office, by center.

Table 3-2. Workload Driver Submission and Inspection Categories Allowed for User Fee Setting as Specified in Statute

PDUFA CDER and CBER CPA Workload Driver Submission Categories	BsUFA CDER CPA Workload Driver Submission Categories	GDUFA CDER Workload Driver Submission Categories	OII GDUFA Workload Driver Submission Categories[8]
• Efficacy Supplements • Labeling Supplements • Manufacturing Supplements • New Drug Applications (NDA)/351(a) Biological License Applications(BLA) Originals • PDUFA Industry Meetings • Active Commercial Investigational New Drug applications (INDs)[1] • Annual Reports[2] • Post Marketing Requirements (PMR)/Post Marketing Commitments (PMC)- Related Documents[2] • Active Risk Evaluation and Management Strategy (REMS) Programs[3]	• Original Biosimilar Supplements (supplements with clinical data and labeling supplements)[4] • Manufacturing Supplements • Biosimilar Biological Product Applications • BsUFA Industry Meetings • Participating Biosimilar Biological Product Development (BPD) Programs • Annual Reports[2] • PMR/PMC Related Documents[2] • Active REMS Programs[3]	• Abbreviated New Drug Applications Originals (ANDAs)[5] • ANDA Supplements[6] • Controlled Correspondence (includes all requesting controlled correspondences) • Pre-ANDA Meetings • Annual Reports[2] • Active REMS Programs[3,7] • Suitability Petitions	• Bioresearch Monitoring Inspections (excluding Analytical) (BIMOs) • Pre-Approval Inspections (PAIs) • Surveillance Inspections

[1] For the purpose of the CPA, this is defined as an active commercial IND for which a document has been received in the past 18 months.
[2] Represents activities related to the review of materials submitted to the application file after approval.
[3] Represents the percentage of active REMS programs proportional to center and user fee by total number of qualifying products with the exclusion of the Opioid Shared System.
[4] Includes Supplements with Clinical Data and Labeling Supplements.
[5] Excludes response to refused to receive (RTR) and Orig-2+. ANDA Original and Resubmissions/Amendments captured in time reporting data.
[6] Includes Changes Being Effected (CBE) and Prior Approval Supplement (PAS) Manufacturing and Labeling Supplements. PAS exclude response to RTR, risk evaluation and mitigation strategies (REMS) and Bioequivalence Supplements. ANDA Supplement and Resubmissions/Amendments captured in time reporting data.
[7] Data represents workload related to resource needs for post-marketing safety activities (developed in alignment with the methodology used in fee-setting under PDUFA (section 736 of the FD&C Act) (*21 U.S.C. 379h*) and BsUFA (section 744H of the FD&C Act) (*21 U.S.C. 379j-52*)), as applicable.
[8] The OII GDUFA methodology has not been implemented yet.

- Number of FTEs currently available: based on hours that current staff work, planned hiring, expected attrition, and a direct effort percentage, converts hours of work to FTEs currently available (i.e., available review staff plus funded vacancies).
- FTE delta (number of additional FTEs needed): the number of FTEs needed to perform the forecasted workload minus the number of FTEs currently available.

Later, after the fiscal year passes, FDA conducts variance analyses: it compares the forecasts from the algorithm engine to actual values to understand and analyze differences and explore potential opportunities for enhancing the models used in the algorithm engine. ERG analyzed these variance data as well (see Appendix B).

Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)

In Step 3, FDA determines whether and how to adjust the FTE delta (resulting in the adjusted FTE delta) based on knowledge and insights that cannot readily be programmed into the algorithm engine (Figure 3-3). This step occurs in FDA's "managerial adjustment" process. FDA uses a rigorous and thoughtful process to consider the reasonableness of the FTE delta based on:

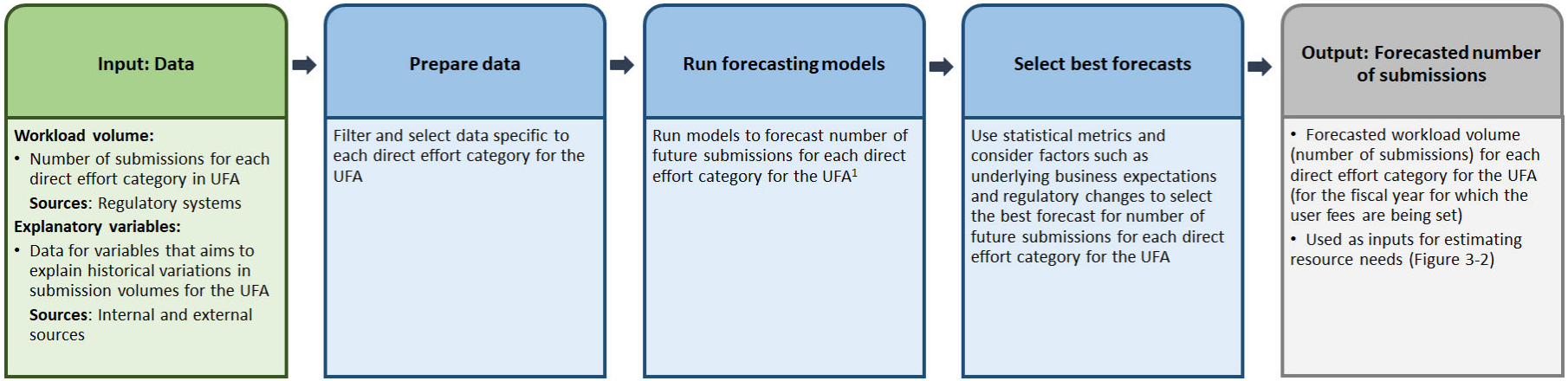
- The accuracy of the FTE delta and CPA for the previous two fiscal years (when available).
- Patterns in workload and FTE forecasts (including whether any increases represent spikes rather than more sustained growth).
- Resource obtainability, including hiring capacity and UFA-funded position vacancies.
- Other factors that could impact resource needs.

To date, the managerial adjustment has always resulted in a downward adjustment; it has not been used to increase the FTE delta.

Step 4. Calculate CPA

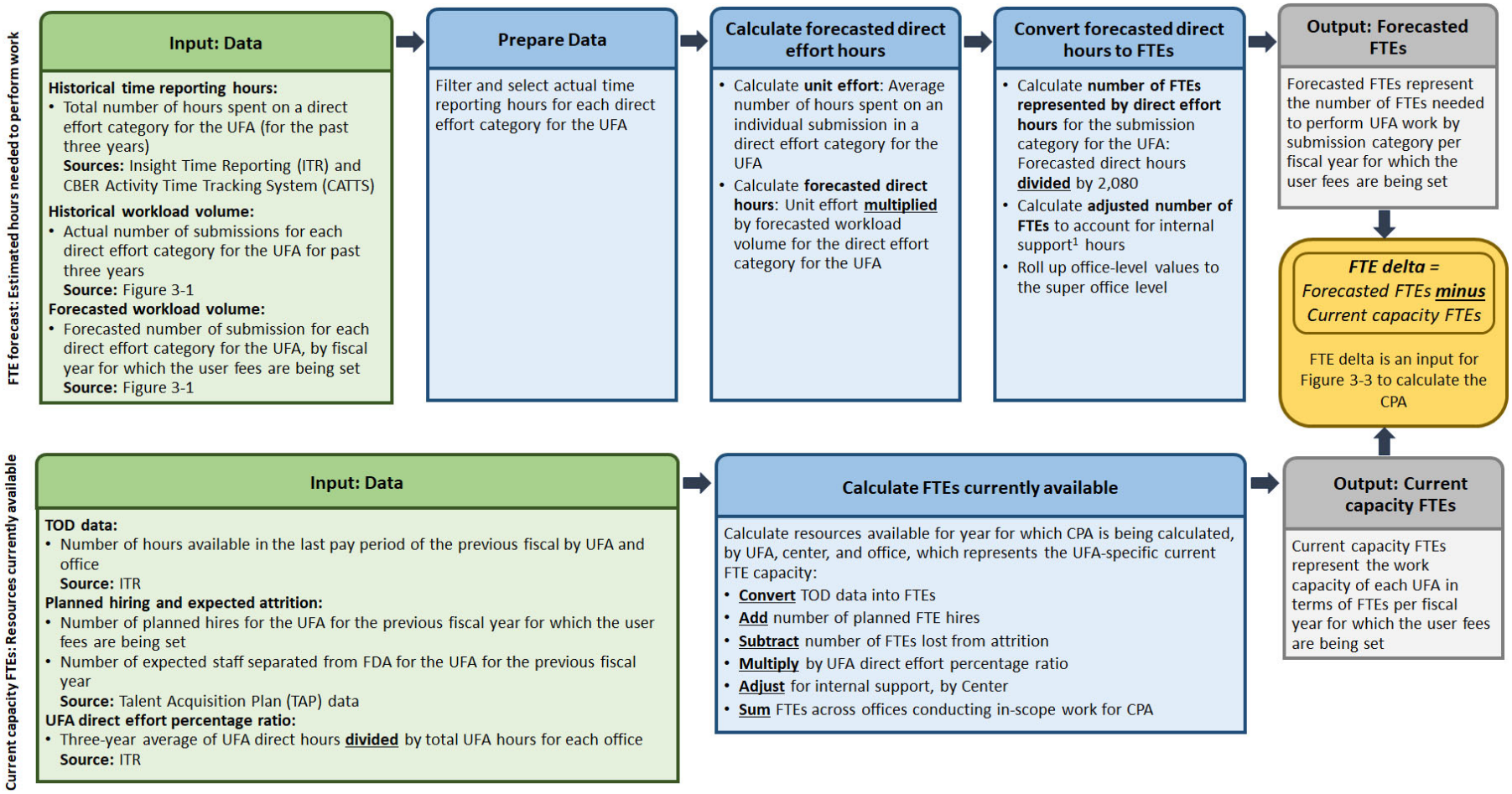
In Step 4, FDA multiplies the adjusted FTE delta by the full cost of an FTE for each center; this produces the CPA for the UFA (Figure 3-3). For PDUFA, in-scope work occurs in both CDER and CBER, so FDA multiplies a center-specific FTE cost by the center-specific adjusted FTE delta to obtain the CPA for that center, then sums the values to generate the PDUFA CPA. This final adjusted CPA reflects each center's judgement about the number of FTEs that the center needs and can feasibly add. The final adjusted CPA can be zero if the final adjusted FTE delta is zero.

Figure 3-1. CPA Methodology Step 1: FDA's Process for Forecasting Workload Volume



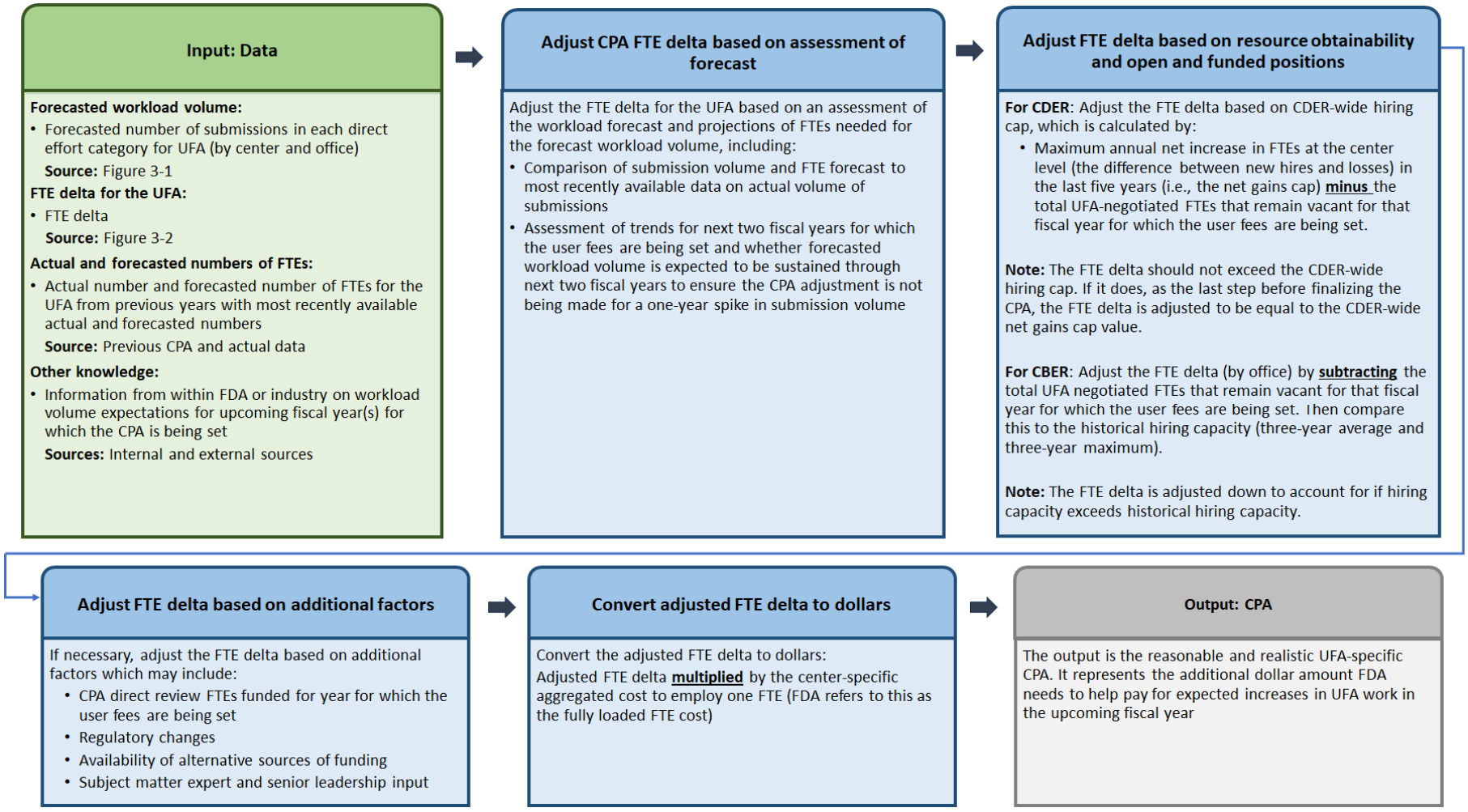
[1] FDA forecasts submission volumes for the next three and half years to support longer term resource planning.

Figure 3-2. CPA Methodology Step 2: FDA's Process for Estimating Additional FTEs Needed



[1] Internal support includes training and professional development, leave, and general and administrative activities.

Figure 3-3. CPA Methodology Steps 3 and 4: FDA's Process to Adjust Estimate of FTE Delta and Calculate CPA



4. Assessment Questions and Answers

4.1 Evaluate the ability of the CPA to forecast PDUFA, BsUFA, and GDUFA resource needs

1. To what extent has the CPA approximated actual changes in FDA workload for the PDUFA/BsUFA/GDUFA program from inception of the CPA to present?

To date, FDA's CPA methodology has produced resource forecasts (as measured by FTEs adjusted for internal support) that fall within 10 percent of actual values. This has been true every year since the CPA's inception for PDUFA (FY2021-present), BsUFA (FY2021-present), and GDUFA (FY2024-present). Moreover, the CPA methodology achieved "Very High" or "High" ratings for all nine evaluation metrics. Table 4-1 presents results for these metrics. ERG concludes that the CPA methodology approximates actual changes in FDA workload reliably and accurately.

Table 4-1. Assessment of CPA Methodology: Key Metrics

Metrics	Rating[1]	Reason for Rating
Accuracy	PDUFA: Very High BsUFA: High GDUFA: Very High	Results demonstrate that: • PDUFA and GDUFA: Submission volume and FTEs forecasts generally fall within a 10 percent of actual values. • BsUFA: Submission volume and FTEs forecasts are generally under forecasted, but this is due to the small volume of submissions and the lack of historical data when initial submission forecast models were developed rather than any flaw in the methodology. • Time reporting and managerial adjustments contribute to the accuracy of the CPA methodology. • FDA's improvements to the CPA methodology over time have increased the accuracy of the CPA.
Breadth	Very High	UFA hours in scope for the CPA as a percentage of all UFA hours are generally consistent year to year. Therefore, the workload drivers in the CPA methodology are a good representation of UFA workload.
Defensibility	Very High	The foundational assumptions underlying the CPA methodology (including workload forecasting, time reporting, algorithm engine, and managerial adjustment) are sound.
Feasibility	Very High	The CPA methodology uses existing tools and resources. Successful use of the methodology also demonstrates feasibility.
Stability	Very High	The CPA methodology includes appropriate automated process steps (for workload forecasting and FTE estimation) and consideration of factors that cannot be automated (in the managerial adjustment). Approaches such as use of three years of historical data to calculate unit effort also contribute to stability.

Metrics	Rating[1]	Reason for Rating
Predictability	Very High	Industry and FDA can reasonably anticipate the magnitude of the adjustment because the CPA methodology uses historical data, uses accurate time reporting data, and includes steps to ensure realistic projections and estimates.
Straightforward-ness	High	The CPA methodology is reasonably straightforward; processes are standardized and easily repeated, with some steps automated. Efforts are underway to further standardize and automate processes. Workload forecasting is complex, but only to the extent required to obtain accurate and reliable workload forecasts.
Transparency	High	***Internal Transparency:*** The CPA methodology is well documented, with steps (including workload forecasting, time reporting system, algorithm engine, and managerial adjustment) described in detail. The documentation could benefit from consolidation, improved formatting, standardization of terms used, and some clarifications. Assumptions and updates are often (but not always) documented. ***External Transparency:*** Public documents on the CPA methodology provide clear information that enable external parties to understand and feel confident in the methodology at a conceptual level. Listing the factors considered during the managerial adjustment for a given year and how each step impacted the forecasted FTEs delta would be helpful; FDA could develop a high-level summary table that shows each of the factors considered during the managerial adjustment and the general outcome of each step and its impact on forecasted FTEs. FDA could publish this information in the Federal Register (if it's not available when the public meeting takes place).
Flexibility	Very High	The CPA methodology can accommodate future changes in workload given built-in flexibility in workload forecasting, time reporting, and the managerial adjustment.

[1] Unless otherwise indicated, rating applies to all three UFAs (PDUFA, BsUFA, and GDUFA) and both CDER and CBER.

2. To what extent have the workload drivers in the CPA represented the actual work of these UFA programs from inception of the CPA to present?

The workload drivers in the CPA methodology (a set of direct work categories statutorily allowed to be included) are reasonably a good representation of overall workload for each UFA. Overall, UFA hours in scope for the CPA represent 25 percent to 42 percent of all UFA hours (Table 4-2); the percentages are lower for BsUFA than for PDUFA and GDUFA. For each UFA, the percentages remain reasonably consistent year over year, fluctuating by 4 percent or less each year.

The remaining 58 to 75 percent of UFA hours consist of workload activities that are not in-scope for the CPA, such as general and administrative activities, leave, internal improvement projects, science and research, policy and guidance, and training and development.

Table 4-2. UFA-Allowable Work Hours as a Percent of Total Work Hours for the UFA, by UFA and Fiscal Year

UFA Program	FY2020	FY2021	FY2022	FY2023	FY2024
PDUFA - CDER	42%	41%	38%	38%	38%
PDUFA - CBER	32%	31%	31%	32%	36%
BsUFA	29%	27%	26%	25%	29%
GDUFA	42%	40%	39%	38%	39%

3. In what ways might workload drivers change in upcoming PDUFA/BsUFA/GDUFA years, and how might those changes impact CPA performance?

Over the years, drivers of UFA workload have evolved as FDA has introduced new types of meetings and submissions, generated new areas of expertise, and adjusted review processes to meet the needs of a changing medical product development landscape. ERG cannot predict how workload drivers might change in upcoming years, but we assume that changes will occur—and the CPA methodology must be able to adapt to those changes.

The CPA methodology is sufficiently flexible to accommodate the types of changes in workload drivers that have occurred in the past and could occur in the future. Specifically, the methodology can accommodate:

- Changes in the relative volume of different types of submissions and other allowable work activities.
- Addition (or deletion) of workload drivers if necessary. FDA might need to develop new models to accommodate new drivers, but the methodology provides a structural and conceptual foundation for doing so.
- New account codes in FDA's time reporting system if new codes need to be added to accommodate changes in drivers.
- Unforeseen changes in submission volume or average review staff salary (e.g., if the volume of submissions requiring higher paid expert increases) by means of the managerial adjustment. To date, FDA has not needed to use the managerial adjustment to address these types of changes, but could do so if necessary.

ERG concludes that the structure and flexibility of the CPA methodology, with the inclusion of a managerial adjustment, provide a sound basis for continued performance at high levels.

4.2 Evaluate the opportunities for the enhancement of time reporting toward informing resource needs.

4. What (if any) changes to FDA's time reporting system or practices would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts?

FDA has modernized its time reporting system to improve accuracy in reporting and resource forecasting for PDUFA, BsUFA, and GDUFA. Continuation of FDA's modernization efforts and daily time entry could produce incremental improvements in time reporting data to further support resource forecasts.

FDA uses its modernized time reporting system, Insight Time Reporting (ITR), to obtain counts of hours for UFA resource forecasts. From a user perspective, ITR has a user-friendly interface, has automated accuracy checks (data validations), and includes convenient features for copying or deleting time reporting activities. From an agency data infrastructure perspective, it includes technological advancements such as automatic links to regulatory databases and integration into FDA's CDEROne analytical environment. From an analytical perspective, it captures enough detail to accurately predict unit effort for the CPA methodology while still minimizing the burden of time reporting for users. Within CBER and CDER, each office has guides for best practices for use of the time reporting system.

ERG concludes that FDA's time reporting system and practices contribute to the high degree of accuracy of CPA methodology forecasts of UFA resource needs. To minimize the burden and maximize the efficiency of detailed time reporting, the agency requires staff to record their daily work activities by the end of each two-week pay period. FDA's goal is for 95 percent of ITR users to do so; most offices meet this goal consistently, while some underperform consistently or occasionally.

FDA encourages staff to record their hours daily, but does not require this. Depending on their preference and role (and number of activities they perform), some staff record their time daily, while others record their time at the end of each pay period. ERG suggests that FDA continue to encourage staff to record their hours daily when it is practical to do so, while still providing flexibility for staff for whom this would be burdensome. Increased daily recording of hours could further increase compliance with time reporting goals and incrementally improve the accuracy of time reporting data.

4.3 Evaluate the integration and utilization of RCP information within resource and operational decision-making processes of the PDUFA, GDUFA, and BsUFA programs.

5. How does FDA use its RCP capability for other PDUFA/BsUFA/GDUFA resource and operational decision-making processes?

For other PDUFA, BsUFA, and GDUFA resource and operational decision-making processes beyond calculating the CPA for user fee setting, FDA uses its RCP capability to:

- **Quantify resource utilization and forecast resource needs in specific offices and divisions** based on past, present, and future trends and fluctuations in workload. For example, RCP staff produce recurring, ad hoc, and customized analyses of time reporting data that offices and divisions use to understand and plan for resource needs. RCP staff also produce models to facilitate resource allocation and forecasting, which offices also use for resource and operational planning. The RCP team's analyses also help super offices or offices determine how to shift workload across offices/divisions to optimize operations.

- **Guide financial operations.** For example, FDA calculates process cost percentages (percentage of total cost that UFA processes represent) to support UFA budgeting, implementation, and overall financial management. FDA's leadership has reviewed and approved the RCP's methodologies for these calculations, which are based on time reporting data. The results also help assure industry and other interested parties that user fee setting is data-driven and not arbitrary.

6. What (if any) changes to FDA's RCP capability would improve FDA's PDUFA/BsUFA/GDUFA resource forecasts and related operational decision-making processes?

The RCP team's analytical models and reports have been well received by users. RCP staff could replicate the models to improve resource and operational decisions for other super offices and offices. This could help other offices understand resource allocation processes and make decisions based on the same principles. Continuing to work with office leaders/staff will facilitate ongoing improvements to existing models and replicability of additional models.

FDA's RCP team has a structured process for testing and choosing workload forecasts, adjusting them based on external factors, and providing information to support decision-making processes. These capabilities have been helpful and well received by users. RCP staff have been providing information about their needs and requirements to the FDA technology team that is building and supporting OneNexus and CDEROne; continuing to do so will be helpful to ensure that these platforms support efficient RCP work. OneNexus will serve as an improved user interface to manage workflows and route data from the Document Archiving, Reporting and Regulatory Tracking System (DARRTS) and other repositories. CDEROne centralizes the data analysis processes needed for RCP. Having these capabilities in one place could improve user experience, improve the speed of data processing, and facilitate speedier model testing and development of data insights (including workload forecasts). This could lead to more centralized and accurate workload forecasts.

7. What (if any) changes to FDA's RCP capability would improve its utility for other operational decision-making processes?

FDA's UFA financial planning processes are strong methodologically, well established, consistently applied, and widely considered accurate. ERG does not recommend additional changes.

5. Findings and Recommendations

This section provides findings and recommendations for FDA's RCP capability, categorized by type (overarching, UFA specific). Overall, ERG finds that the CPA methodology and FDA's broader RCP capability perform well. Our recommendations are minor in nature.

Table 5-1. Findings and Recommendations

Number	Finding	Recommendation(s)
Overarching		
O1	Overall, the CPA methodology performs well in forecasting workload and resource needs. The workload drivers are a reasonably good representation of overall workload for each UFA.	No action needed.
O2	FDA maintains complete, thorough, and accurate documentation of the CPA methodology. The agency also maintains a complete repository of data used as inputs, CPA methodology results, analyses of CPA performance, and updates to the CPA methodology. Further organizing and streamlining CPA methodology documentation could benefit RCP staff (especially those new to the CPA methodology).	Further organize and streamline internal documentation of the CPA methodology by: • Consolidating and standardizing the format of the documents. • Adding visual aids to show relationships to steps in the CPA methodology. • Standardizing and defining terms. • Adding version numbers and dates to track updates.
O3	The time reporting system is easy to use, flexible, and provides accurate time reporting data. FDA currently encourages daily time reporting and requires staff to record their hours at the end of each two-week tour of duty (TOD).	Continue to encourage daily time reporting to potentially further improve the accuracy and reliability of time reporting data, but allow for flexibility for FDA staff for whom this too burdensome due to their role. FDA could explore sending daily reminders to staff, close to the end of the business day.
O4	RCP capability for financial planning is well established, well received, and useful.	No action needed.
O5	FDA's RCP capability is well positioned to meet future needs for resource and operational decision-making. RCP staff are strategic in anticipating needs and how to best meet them. For example, FDA is: • Expanding use of RCP for resource and operational and decision-making. Reports and data-driven models are useful, with minor recommendations for improvements.	Incorporate the minor improvements recommended to resource forecasting models suggested by users. Determine how similar resource forecasting models might be incorporated elsewhere in FDA (e.g., CDER or CBER offices that do not currently utilize these models) for operational and resource-decision making. Continue RCP modernization initiatives, including analytical models and simulation approaches and migrating

Number	Finding	Recommendation(s)
	• Working on developing analytical models and simulation approaches to test opportunities for more efficient and effective regulatory operations, such as managing industry meetings. • Providing FDA technology teams with needs and suggestions to facilitate building a centralized CDER analytical environment that enables faster data processing and use of more models for RCP-related work. CBER will undertake a similar initiative. An effort to migrate to a centralized workflow management platform is also in development.	processes and data to the CDEROne and OneNexus environments.
UFA-specific		
S1	For PDUFA, CBER is working on maturing its RCP capability (similar to efforts implemented by CDER).	No action needed. CBER is already working to mature its RCP capability.
S2	The CPA methodology performs well for all three UFAs. The CPA methodology for BsUFA tends to under forecast BsUFA workload, but this is due to the small volume of submissions and the lack of historical data when FDA developed the initial submission forecast models rather than any flaw in the methodology.	Now that FDA has some years of historical data, revisit the BsUFA models and methodologies.

Appendix A. Acronyms

A.1 Acronyms

Acronym	Term
ANDA	Abbreviated New Drug Application
BIMO	Bioresearch Monitoring Inspections
BLA	Biologics License Application
BPD	Biosimilar Biological Product Development
BsUFA	Biosimilar User Fee Act
CATTS	CBER Activity Time Tracking System
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CPA	Capacity Planning Adjustment
DARRTS	Document Archiving, Reporting and Regulatory Tracking System
FACTS	Field Accomplishments and Compliance Tracking System
FAQs	Frequently Asked Questions
FDA	Food and Drug Administration
FTE	Full-time equivalent
FY	Fiscal Year
GDUFA	Generic Drug User Fee Amendments
IND	Investigational New Drug
ITR	Insight Time Reporting
NDA	New Drug Application
OBMI	Office of Bioresearch Monitoring Inspectorate
OII	Office of Inspections and Investigations
OMB	Office of Management and Budget
OND	Office of New Drugs
OTBB	Office of Therapeutic Biologics and Biosimilars
PAC	Program activity code
PAI	Pre-Approval Inspections
PDUFA	Prescription Drug User Fee Act
PMC	Post Market Commitment
PMR	Post Market Requirement
PSG	Product-Specific Guidance

Acronym	Term
RCP	Resource Capacity Planning
REMS	Risk Evaluation and Mitigation Strategy
RTR	Refused to Receive
SOP	Standard Operating Procedures
SURV	Surveillance
TAP	Talent Acquisition Plan
TOD	Tour of Duty
UFA	User Fee Act

Appendix B. Results Supporting Evaluation

In this appendix, ERG presents evaluation results as follows:

- Section B.1 CPA Methodology
    - Section B.1.1 Accuracy
    - Section B.1.2 Breadth
    - Section B.1.3 Defensibility
    - Section B.1.4 Feasibility
    - Section B.1.5 Stability
    - Section B.1.6 Predictability
    - Section B.1.7 Straightforwardness
    - Section B.1.8 Transparency
    - Section B.1.9 Flexibility
- Section B.2 Time Reporting Systems
- Section B.3 RCP Capabilities for Resource and Operational Decision-Making
    - Section B.3.1 Financial Planning and Management Processes
    - Section B.3.2 Resource Needs Assessments and Related Operational Decision-Making Processes
    - Section B.3.3 Overarching RCP Strengths
    - Section B.3.4 Future Considerations

B.1 CPA Methodology

This appendix focuses on the first three steps in the CPA methodology because they involve large amounts of data and numerous models and processes. The fourth step in the CPA methodology (convert adjusted FTEs to dollars) is a simple, well documented calculation that does not require detailed evaluation.

Please see Section 3 of this report for an explanation of the CPA methodology and the terms we use in this appendix.

B.1.1 Accuracy

Accuracy of forecasts for key steps in CPA methodology

The CPA methodology forecasts UFA resource needs by:

1. Predicting the number of submissions in each direct effort category.
2. Estimating the unit effort required for a submission, by direct effort category.
3. Estimating the total number of hours required to perform work for all submissions, by direct effort category (by multiplying unit effort by the predicted number of submissions in a category)—and then converting that total number of hours to FTEs.
4. Adjusting the number of FTEs to account for internal support.

For each UFA, ERG assessed the accuracy of the CPA methodology by comparing forecasted values to actual values for Steps 1, 3, and 4.

Forecasting inherently involves some degree of uncertainty; predictions rarely match actual values exactly. Therefore, ERG established a threshold for CPA methodology accuracy: for key steps in the methodology, we consider forecasted values to be accurate if they fall within 10 percent of actual values.

Workload (submission) volume. For each UFA CPA methodology, forecasted submission volumes generally fall within 10 percent of actual submission volumes for each direct effort category. The BsUFA CPA methodology, however, under forecasted submission volume in FY2024 by 21.6 percent. The annual number of BsUFA submissions is relatively small, and even small changes in the number of submissions can significantly impact percent change calculations. For example, in FY2024, the BsUFA CPA methodology under forecasted Post Approval-REMS by 100 percent: the forecast was zero submissions in FY2024, and the actual was 1.1 submissions. With such a small submission volume, the percent difference between forecasted and actual values is not meaningful.

Direct FTEs. Except for a slight over forecast in FY2022, the PDUFA CPA methodology accurately forecasts the number of direct FTEs each year. The BsUFA CPA methodology under forecasted direct FTEs in FY2023 and FY2024; the limited amount of historical data and the low submission volume make it difficult to produce accurate forecasts. To date, the GDUFA CPA methodology has produced accurate forecasts of direct FTEs.

Adjusted FTEs. In general, patterns in CPA methodology forecasts of adjusted FTEs mirror those for direct FTEs.

Table B-1 presents the percent difference between forecasted and actual values for each year since the CPA methodology's inception. For PDUFA and GDUFA, most forecasts fall within the 10 percent threshold. For BsUFA, most forecasts were 15-25 percent lower than actual values.

Table B-1. Accuracy of CPA Methodology: Percentage Difference Between Actual and Forecasted Submission Volume and FTEs

Variable[1]	PDUFA FY2021	PDUFA FY2022	PDUFA FY2023	PDUFA FY2024	BsUFA FY2023[2]	BsUFA FY2024	GDUFA FY2024
Submission volume: CDER	-1.9%	9.4%	9.3%	-3.1%	2.2%	-21.6%	-6.5%

Variable[1]	PDUFA FY2021	PDUFA FY2022	PDUFA FY2023	PDUFA FY2024	BsUFA FY2023[2]	BsUFA FY2024	GDUFA FY2024
Submission volume: CBER	-1.0%	8.8%	-5.2%	-7.3%	NA	NA	NA
Submission volume: CDER and CBER[3]	-1.8%	9.3%	6.9%	-3.8%	NA	NA	NA
Accuracy assessment[4]	Within threshold	Within threshold	Within threshold	Within threshold	Within threshold	Under forecast	Within threshold
Direct FTEs: CDER	2.8%	13.0%	6.7%	-4.0%	-14.2%	-24.2%	-5.8%
Direct FTEs: CBER	-7.3%	-0.5%	-12.2%	-7.8%	NA	NA	NA
Direct FTEs: CDER and CBER	1.1%	10.7%	3.2%	-4.7%	NA	NA	NA
Accuracy assessment	Within threshold	Over forecast	Within threshold	Within threshold	Under forecast	Under Forecast	Within threshold
Adjusted FTEs[5]: CDER	2.3%	11.0%	1.6%	-4.0%	-17.6%	-24.3%	-5.8%
Adjusted FTEs: CBER	1.9%	3.1%	-15.6%	-7.8%	NA	NA	NA
Adjusted FTEs: CDER and CBER	2.2%	9.6%	-1.8%	-4.7%	NA	NA	NA
Accuracy assessment	Within threshold	Within threshold	Within threshold	Within threshold	Under forecast	Under Forecast	Within threshold

[1] ERG used the actual and predicted values for each category (submission volume, direct FTEs and adjusted FTEs) from each year's retrospective variance analysis. ERG calculated the percentage difference between predicted and actual values as *percentage difference = (forecasted values – actual values)/actual values*. The values reported in Table B-1 might vary very slightly from similar percentage difference calculations in the variance analyses due to rounding.

[2] FDA did not conduct such analyses for BsUFA in FY2021 and FY2022; therefore, we present data only for FY2023 and FY2024.

[3] CDER and CBER percent differences do not sum to combined CDER and CBER values. This is because CDER and CBER values have different denominators. For example: percentage difference for combined CDER and CBER submission volume = ((CDER forecasted submission volume + CBER forecasted submission volume) – (CDER actual submission volume + CBER actual submission volume)) / (CDER actual submission volume + CBER actual submission volume). The same logic applies to the other combined CDER and CBER calculations in this table.

[4] Within threshold means that the forecasted value is within 10 percent of actual value. Over forecast means the forecasted value is greater than 10 percent of the actual value. Under forecast means the forecasted value is 10 percent less than the actual value.

[5] The value for adjusted FTEs is the direct FTEs value adjusted for internal support.

CPA Methodology Components and Processes that Support Accuracy

Time reporting data and systems. The CPA methodology uses data from FDA time reporting systems to calculate the amount of time spent on submissions by fiscal year, submission category, center, and office. ERG examined FDA's time reporting systems, controls, procedures, and data to assess the extent to which they support CPA accuracy:

- **Time reporting systems***:* These systems include ITR for CBER, CDER, and OII, with OII also using Field Accomplishments and Compliance Tracking System (FACTS) and eNSpect, commonly referred to as FACTS/eNSpect. These systems enable FDA staff to report their time at a sufficient level of detail to meet the needs of the CPA methodology. The systems are also sufficiently user-friendly to support accurate reporting.
- **Time reporting controls:** FDA's time reporting data are voluminous. As of October 2022, for PDUFA, BsUFA, and GDUFA, FDA had about 10,600 active time reporting system users, over 470,000 pay period time sheets, and over 13,500,000 time entries. To ensure data accuracy, FDA implements automated and manual controls (e.g., prevent users from reporting more than 24 hours of activities in a day or more than 10 hours of leave in a day). RCP staff manually check entries for correct reporting codes and correct errors.
- **Time reporting practices:** FDA uses good practices for time reporting. Although time reporting is most accurate when recorded daily, FDA does not require daily reporting because this might discourage compliance. Instead, FDA sends automated reminder emails every Tuesday and Thursday to users who have not reported their time. FDA data indicate that 95 percent or more of staff complete time reporting on time.
- **Time reporting data:** In the CPA methodology, models compare current time reporting data with historical patterns to identify and address any issues. To date, this process has revealed no persistent inconsistencies.

Adjust FTE delta. The third step of the CPA methodology, also referred to as the managerial adjustment, supports the accuracy of the CPA by incorporating knowledge and factors that cannot easily be automated into models in the algorithm engine:

- **Internal FDA and industry knowledge.** This includes expert input on industry and submission trends, expected trends for UFA programs, impacts of COVID-19, and trends and special considerations for specific therapeutic areas. For example, PDUFA CBER maintains an internal tracker of major expected submissions to inform trends analyses.
- **Historical hiring capacity.** CDER introduced its net gains cap for PDUFA and BsUFA in FY2023 and GDUFA in FY2024. Based on the previous five years of hiring data, each fiscal year CDER calculates a cap to establish an upper limit on additional FTEs that CDER programs collectively can realistically onboard during the fiscal year. Similarly, CBER considers historical hiring capacity for each office and sets an upper limit as to how many FTEs can realistically be onboarded during the fiscal year.
- **Additional funding source**. FDA considers the extent to which any budget surpluses can fund additional hiring.

- **Forecast analyses.** For PDUFA and BsUFA, FDA analyzes the accuracy of previous workload and FTE projections. In the future, FDA will conduct these analyses GDUFA as well; because FDA implemented the GDUFA CPA methodology in FY2024, data have not been available to do so to date. FDA also generates workload volume forecasts for an additional year to ensure that modeled forecasts are realistic and not unduly influenced by a short-term (e.g., one-year) spike.
- **Hiring status.** To avoid double counting FTEs from previous years, FDA counts and removes the number of FTEs that are currently funded but unfilled or in progress.

For all three UFAs, to date the managerial adjustment has always reduced the adjusted FTE delta.

CPA methodology updates. FDA regularly updates the CPA methodology to improve its accuracy and streamline the process. Examples of updates made to date include the following:

- **Submission forecasting models.** Originally, CDER and CBER used machine learning models to forecast the number of submissions for each direct effort category. This was time-consuming, so the FDA transitioned to less computationally intensive models, including time-series methods.[5] These changes reduced errors and improved accuracy while reducing the amount of manual work and computation time required for submission forecasting. FDA has also implemented toolkits (prebuilt libraries) that improve the replicability and standardization of forecasting models; the toolkits also allow FDA analysts to track the accuracy of the models over time.
- **Time reporting data.** Before FDA implemented ITR, staff reported time during a two-week period each quarter (total of eight weeks per year). The introduction of modernized time reporting year-round has greatly improved the accuracy and volume of time reporting data.
- **Estimate FTE delta.** FDA has instituted**:**
    - Automated accounting for planned hiring and attrition. FDA requires all centers to develop a Talent Acquisition Plan (TAP) to help standardize human resources work at the agency. Starting with the FY2025 CPA, the algorithm engine uses TAP data to account for planned hiring and attrition for each UFA. Previously, FDA staff had to manually consider these factors as part of the managerial adjustment.
    - A consistent percentage to use for internal support for all offices that perform review work (based on a five-year rolling average).
    - Use of unweighted averages to calculate unit effort. Because FDA determined that use of weighted averages by year does not outperform unweighted averages, the algorithm engine now uses unweighted averages to calculate unit effort. This simplifies the process. FDA is working on a unified set of rules for calculating unit effort across submission categories.

[5] These are examples of the covariates used in the multivariate workload forecasting models and not an exhaustive list: number of category-specific submissions and approvals, number of product-specific guidance publications, brand and generic volume and sales, number of upcoming patents expiring, and number of upcoming exclusivities expiring.

- **Automation of analyses**. Over time, FDA has been able to automate some of the factors previously addressed in the managerial adjustment, thereby shifting those factors to the algorithm engine. For PDUFA and BsUFA, as sufficient historical data became available, FDA also added automated analyses of forecasted versus actual submission volumes.

B.1.2 Breadth

The CPA methodology includes a set of workload drivers (direct effort categories) that are statutorily allowed to be included in (also referred to as in scope for) UFA fee setting. ERG examined the extent to which these drivers represent the full amount of UFA work. We did so by calculating the percent of total UFA hours that these drivers represent (by dividing the number of in-scope hours spent by direct review staff on submissions by the total number of hours spent on work for the UFA). As shown in Table B-2 through Table B-5, in-scope hours represent 21 percent to 42 percent of all UFA hours; the percentages are lower for BsUFA than for PDUFA and GDUFA. For each UFA, the percentages are reasonably consistent year over year. Thus, ERG concludes that the workload drivers in the CPA methodology are a reasonably good representation of overall UFA workload.

Table B-2. CDER PDUFA In-Scope CPA Hours Compared to All PDUFA Hours, by Submission Category and Fiscal Year

In-Scope Submission Category	FY2020	FY2021	FY2022	FY2023	FY2024
Efficacy Supplements	168,490	168,590	153,507	165,100	166,975
Labeling Supplements	136,054	134,512	122,367	123,352	146,099
Manufacturing Supplements	144,839	132,798	130,069	138,368	153,956
NDAs/351(a) BLA Originals	643,833	669,623	575,879	676,904	632,827
PDUFA Industry Meetings	188,579	201,387	208,774	197,452	179,072
Active INDs	1,145,515	1,173,401	1,147,343	1,177,450	1,285,956
Annual Reports	8,779	8,362	10,055	9,261	9,763
PMR/PMC-Related Documents	54,454	58,954	54,544	52,237	51,421
Active REMS Programs	29,985	27,601	34,548	32,321	35,384
Total in-scope CPA hours	**2,520,529**	**2,575,228**	**2,437,086**	**2,572,445**	**2,661,453**
Total PDUFA hours (CDER)[1]	**6,002,295**	**6,356,699**	**6,439,861**	**6,701,722**	**6,952,879**
% in-scope CPA hours of total PDUFA hours	**42%**	**41%**	**38%**	**38%**	**38%**

[1] Includes in-scope (direct effort) hours plus other UFA hours, including categories such as general and administrative activities, leave, internal improvement projects, science and research, policy and guidance, and training and development, among others.

Table B-3. CBER PDUFA in-Scope CPA Hours Compared to All PDUFA Hours, by Submission Category and Fiscal Year

In-Scope Submission Category	FY2020	FY2021	FY2022	FY2023	FY2024
Efficacy Supplements	27,057	28,769	41,098	45,889	50,287
Labeling Supplements	8,117	4,881	5,295	6,844	12,088
Manufacturing Supplements	73,836	77,715	79,732	74,634	88,692
NDAs/351(a) BLA Originals	75,999	79,347	76,465	152,968	122,933
PDUFA Industry Meetings	32,963	26,645	24,879	23,196	43,772
Active INDs	249,603	276,349	281,239	269,149	292,758
Annual Reports	12,056	17,370	14,369	12,877	12,704
PMR/PMC-Related Documents	4,613	2,630	3,679	3,844	4,573
Active REMS Programs	475	767	1,067	633	841
Total in-scope hours	**484,719**	**514,473**	**527,823**	**590,034**	**628,648**
Total PDUFA hours (CBER) [1]	**1,532,929**	**1,672,340**	**1,710,923**	**1,817,284**	**1,770,012**
% in-scope CPA hours of total PDUFA hours	**32%**	**31%**	**31%**	**32%**	**36%**

[1] Includes in-scope (direct effort) hours plus other UFA hours, including categories such as general and administrative activities, leave, science and research, policy and guidance, and training and development, among others.

Table B-4. CDER BsUFA in-Scope CPA Hours Compared to all BsUFA Hours, by Submission Category and Fiscal Year

In-Scope Submission Category	FY2020	FY2021	FY2022	FY2023	FY2024
Biosimilar Supplements Category A to F	NA	NA	NA	2,131	5,425
Manufacturing Supplements	10,477	8,898	8,221	6,783	9,202
Efficacy Supplements	1,454	4,131	4,786	3,979	3,714
Labeling Supplements	2,816	3,559	2,802	3,134	3,660
Biosimilar Biological Product Applications	31,205	42,201	42,816	63,909	78,545
BsUFA Industry Meetings	17,291	15,881	15,427	11,580	18,796
Participating Biosimilar Biological Product Development (BPD) Programs	13,648	11,927	15,211	19,467	20,518
Annual Reports	152	362	109	176	95
PMR/PMC-Related Documents	376	439	395	188	246
Active REMS Programs	304	333	359	1,163	1,910
Total in-scope hours	**77,865**	**87,530**	**89,965**	**111,634**	**140,509**
Total BsUFA hours[1]	**264,850**	**319,840**	**347,489**	**449,350**	**482,678**

In-Scope Submission Category	FY2020	FY2021	FY2022	FY2023	FY2024
% in-scope CPA hours of total BsUFA Hours	**29%**	**27%**	**26%**	**25%**	**29%**

[1] Includes in-scope (direct effort) hours plus other UFA hours, including categories such as general and administrative activities, leave, internal improvement projects, science and research, policy and guidance, and training and development, among others.

Table B-5. CDER GDUFA in-Scope CPA Hours Compared to all GDUFA Hours, by Submission Category and Fiscal Year

In-Scope Submission Category	FY2020	FY2021	FY2022	FY2023	FY2024
ANDA Supplements	157,845	165,872	151,788	176,498	208,282
ANDA Originals	1,165,557	1,058,751	1,006,897	974,121	1,016,227
Controlled Correspondence	68,987	77,049	68,282	78,431	87,553
Pre-ANDA Meetings	26,204	27,541	25,332	25,873	25,945
Annual Reports	49	96	144	114	107
Active REMS Programs	19,755	23,926	18,786	23,652	30,055
Suitability Petitions	2,918	3,820	1,997	2,429	11,307
Total in-scope hours	**1,441,315**	**1,357,055**	**1,273,226**	**1,281,118**	**1,379,476**
Total GDUFA Hours[1]	**3,405,939**	**3,352,903**	**3,259,500**	**3,413,059**	**3,581,332**
% in-scope CPA hours of total GDUFA hours	**42%**	**40%**	**39%**	**38%**	**39%**

[1] Includes in-scope (direct effort) hours plus other UFA hours, including categories such as general and administrative activities, leave, internal improvement projects, science and research, policy and guidance, and training and development, among others.

B.1.3 Defensibility

Defensibility is the extent to which the assumptions that form the basis of the CPA methodology can be reasonably expected to be valid. Below we examine the defensibility of four aspects of the CPA methodology:

- **Workload volume forecasting.** CPA methodology documentation (organized by UFA, center, and submission type or direct effort category) describes the models used for submission volume forecasting, procedures for running the models, and potential future enhancements. FDA runs the forecast models twice each year: first in October as dry run to test new enhancements, then in April to produce the CPA for the UFA. In so doing, FDA compares several models for each forecasted submission type (with different analytical methodologies)—and compares the top-performing model to a historical three-year average. FDA has standardized forecast modeling within Databricks, and RCP analysts have shared access to its automated data pipelines, which facilitates running and

selecting models in a repeatable fashion. Data indicate that submission volume forecasting is reliable and accurate.

- **Time reporting data.** FDA uses modernized time reporting systems with controls to minimize human error; the agency consistently meets timesheet compliance goals. This helps the agency track hours spent on direct review work reliably and accurately.
- **Estimate FTE delta.** For each UFA and center, FDA maintains documentation of the CPA methodology's algorithm engine. As with submission forecasting, FDA runs the algorithm engine twice each year (in October to test enhancements and in April to calculate the CPA). The algorithm engine has several built-in data quality checks and RCP staff perform additional checks manually based on documented procedures. Data analyses indicate that the algorithm engine produces reliable, accurate results.
- **Adjust FTE delta.** The managerial adjustment accounts for factors not considered in the algorithm engine (Table B-6).

Table B-6. Defensibility of CPA Methodology

Evidence of Defensibility	PDUFA	BsUFA	GDUFA
Step 1. Forecast workload (submission) volume			
• Forecasting methodology and process for selecting the optimal models are well documented, well defined, reasonable, and organized. o FDA runs the methodology twice a year to test performance in addition to producing the CPA. o FDA uses statistical validation metrics to select the best model for a given year (to reduce error and optimize accuracy). The process also involves expert consideration of external factors such as shifts in industry, regulatory changes, or model diagnostics. o Automated data pipelines in Databricks help FDA run the models efficiently and with reproducibility.	✓	✓	✓
• Models generate reliably accurate results for all years with data.	✓		✓
Step 2. Estimate additional FTEs needed for forecasted workload volume (FTE delta)			
Time reporting data: • Modernized time reporting provides reliable, accurate data for algorithm engine. o Manual and automated quality control checks and processes help prevent errors in time reporting data. o Compliance with time reporting requirements is high (at least 95%).	✓	✓	✓
Algorithm engine: • Steps for refreshing the algorithm engine are well-defined, reasonable, and documented: o FDA publishes documentation of the technical design and standard operating procedures (SOPs) for the algorithm engine annually.	✓	✓	✓

Evidence of Defensibility	PDUFA	BsUFA	GDUFA
o Running the algorithm engine twice annually for performance testing helps FDA identify and implement improvements and ensure defensibility of results. o The algorithm engine R scripts have built in data quality checks. Additional manual data quality checks are also performed.			
Algorithm engine: • The algorithm engine accurately predicts FTEs adjusted for internal support for all years with data.	✓		✓
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)			
• The managerial adjustment considers a retrospective analysis of the accuracy of the workload and FTE forecasts.	✓	✓	✓
• FDA generates forecasts for an additional year to assess whether they are realistic (and not driven by single-year spikes).	✓	✓	✓
• CDER applies a hiring limit based on the maximum number of FTEs they can realistically onboard; CBER also considers hiring capacity for each office.	✓	✓	✓

B.1.4 Feasibility

The CPA methodology's use of current FDA data, tools, programs, and other resources demonstrates feasibility.

Table B-7. Feasibility of CPA Methodology

Evidence of Feasibility	PDUFA	BsUFA	GDUFA
Step 1. Forecast workload (submission) volume			
• Data come from established and organized data sources and are processed in CDEROne, an organized central system, using Databricks.	✓	✓	✓
• FDA saves calculations on a local shared drive or Amazon Web Services (AWS) GovCloud.	✓	✓	✓
• Staff working on the workload forecasting models is identifiable and tracked.	✓	✓	✓
• Forecasting models use well known, reliable programs (e.g., R Studio, Excel, and Python).	✓	✓	✓
• FDA provides training and documentation to support staff in learning and running forecasting models.	✓	✓	✓

Evidence of Feasibility	PDUFA	BsUFA	GDUFA
Step 2. Estimate additional FTEs needed for forecasted workload volume (FTE delta)			
Time reporting data: • Data comes from a reliable, accurate time reporting system.	✓	✓	✓
Algorithm engine: • Algorithm engine's use of R Scripts and Excel configuration files helps optimize efficiency and traceability.	✓	✓	✓
Algorithm engine: • Algorithm's use of hiring and attrition (TAP) data supports feasibility by avoiding unnecessary manual work.	✓	✓	✓
• Documentation helps support staff in learning and implementing the algorithm engine; the documentation could be improved for greater clarity.	✓	✓	✓
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)			
• Managerial adjustment incorporates available analyses and resources (e.g., retrospective analyses, CBER's anticipated submissions tracker, hiring trends, and expert/leadership's opinions).	✓	✓	✓

B.1.5 Stability

Several factors support the stability of the CPA methodology (Table B-8):

- **Workload volume forecasting.** Use of historical data, along with consideration of factors that mitigate potential sources of volatility, help ensure the stability of submission volume forecasts.
- **Time reporting data.** Use of actual hours (from time reporting data) helps ensure that forecasts of resource needs are reasonable based on time actually required for the range of submissions (within each direct effort category) that FDA receives.
- **Estimate FTE delta.** Use of three-year averages to calculate unit effort helps minimize volatility, as does analysis of performance results in periodic tests of the algorithm engine.
- **Adjust FTE delta.** The managerial adjustment involves several steps to minimize volatility.

Table B-8. Stability of CPA Methodology

Evidence of Stability	PDUFA	BsUFA	GDUFA
Step 1. Forecast workload (submission) volume			
• Models consider historical performance, business expectations, and external factors (such as regulatory changes).	✓	✓	✓
• FDA adds models when UFA reauthorizations add new categories of work (e.g., REMS, Post Approval Activities).	✓	✓	✓
• Methodology addresses spikes in volume if they occur; univariate, multivariate, exponential smoothing, and time series methods to identify trends and shifts.	✓	✓	✓
Step 2. Estimate additional FTEs needed for forecasted workload volume (FTE delta)			
Time reporting data: • Time reporting system provides data on actual work completed.	✓	✓	✓
Algorithm engine: • Use of averaged values of historical time reporting data to forecast future trends reduces impact of single year spikes.	✓	✓	✓
Algorithm engine: • Running the CPA methodology twice each year gives FDA time to identify and address any volatility before running it to produce the CPA.	✓	✓	✓
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)			
• FDA generates estimates for an additional year to determine whether workload spikes are temporary anomalies or long-term trends. Analyses of historical and current data help assess and verify stability of the methodology.	✓	✓	✓
• CBER's anticipated submissions tracker helped inform forecasting as a source of supplementary information, which was especially useful for BLA submissions (a category that has been challenging to forecast). For the FY2025 CPA and moving forward, sufficient retrospective analyses confirmed that the BLA forecast consistently outperformed the tracker.	✓		
• FDA takes into account external factors that might cause volatility, especially for PDUFA (e.g., regulatory changes, trends in specific therapeutic areas, impact of current events, immigration/credential processes when hiring foreign nationals).	✓	✓	✓
• Instead of making broad workforce increases, the adjustment process identifies specific super offices and offices where additional resources are needed, reducing unnecessary fluctuation in workforce levels.	✓	✓	✓
• Applying the CDER net gains cap accounts for center-wide hiring trends. Basing the cap on multi-year hiring data prevents large swings in FTE allocations year to year and helps maintain consistency in workforce planning. CBER also reviews net gains hires and consults SMEs as appropriate.	✓	✓	✓

B.1.6 Predictability

Several factors contribute to the predictability of the CPA methodology (Table B-9):

- **Workload volume forecasting.** The CPA methodology's forecast models consistently generate accurate values that are consistent with what experts might predict. When events or factors arise that models cannot predict, FDA uses the managerial adjustment to account for those issues.
- **Time reporting data**. The use of a modernized time reporting system generates accurate data on hours spent on submissions, which support the predictability of the CPA methodology and its outputs.
- **Estimate FTE delta.** The algorithm engine incorporates additional data and calculations (e.g., TAP data) that help support predictability of the CPA. Running the model twice each year provides opportunities for performance testing and improvement, further supporting predictability.
- **Adjusted FTE delta.** The managerial adjustment step assesses the FTE delta and adjusts it as necessary to ensure the reasonableness of the result (**Error! Reference source not found.**). The managerial adjustment has always resulted in a downward adjustment; it has not been used to increase the FTE delta.

Table B-9. Predictability of CPA Methodology

Evidence of Predictability	PDUFA	BsUFA	GDUFA
Step 1. Forecast workload (submission) volume			
• Use of historical trends in forecasting supports predictability.	✓	✓	✓
Step 2. Estimate additional FTEs needed for forecasted workload volume (FTE delta)			
Time reporting data: • Calculation of unit effort based on accurate, reliable time reporting data provides a sound basis for calculating the FTE delta.	✓	✓	✓
Algorithm engine: • Running the algorithm engine twice each year provides opportunities for performance testing and improvement, which supports predictability.	✓	✓	✓
Algorithm engine: • Integration of TAP (accounts for planned hiring) and attrition by office.	✓	✓	✓
Algorithm engine: • Use of historical averages to calculate/assess unit effort helps support predictability.	✓	✓	✓
Algorithm engine: • The algorithm engine accounts for internal support across all super offices and offices and does so consistently.	✓	✓	✓

Evidence of Predictability	PDUFA	BsUFA	GDUFA
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)			
• Analyses of performance of the CPA methodology support predictability.	✓	✓	✓
• Use of the CDER net gains cap supports realistic projections of potential hires.	✓	✓	✓
• Use of the CBER anticipated submissions tracker supports realistic estimation of submission volumes for difficult-to-predict categories such as BLAs. For the FY2025 CPA and moving forward, sufficient retrospective analyses confirmed that the BLA forecast consistently outperformed the tracker.	✓		
• The managerial adjustment considers whether the next fiscal year will have a budget surplus by determining if a current surplus will continue into the following year, but this is difficult to predict.	✓	✓	

Table B-10. Comparison of FTE Delta and Adjusted FTE Delta by UFA, Fiscal Year, and Office

Fiscal Year	Center	FTE delta (before managerial adjustment)	Adjusted FTE delta (after managerial adjustment)	Change in delta (%)
PDUFA				
2021	CDER	265.5	13	-95%
	CBER	62.4	29	-54%
2022	CDER	175.4	78	-56%
	CBER	59.7	7	-88%
2023	CDER	151	27	-82%
	CBER	9.4	10[6]	6%
2024	CDER	69.8	38	-46%
	CBER	43.9	34	-23%
BsUFA				
2021	CDER	26.5	0	-100%
2022	CDER	17.4	0	-100%
2023	CDER	16	0	-100%
2024	CDER	9	0	-100%
GDUFA				
2024	CDER	34.6	25	-28%

[6] In FY2023, CBER rounded the adjusted FTE delta of 9.4 to 10, given the inability to hire a partial FTE.

B.1.7 Straightforwardness

Several factors contribute to the straightforwardness of the CPA methodology (Table B-11):

- **Workload (submission) volume forecasting.** The CPA methodology's forecasting models are complex and require an understanding of statistics, including concepts such as time series, machine learning methods, demand forecasting, and other methodologies. These are necessary to ensure accurate, reliable results. A prerequisite for hiring an RCP analyst is having foundational data science skills, such as a high proficiency with programming, statistics and relevant technology. In addition, RCP analysts receive training and a toolkit (including prebuilt libraries of codes) to facilitate running the models. Over time, FDA has been able to improve and streamline the models and automate some previously manual process steps. FDA continues to improve the explainability of the models.
- **Time reporting data.** FDA's modernized time reporting system is user-friendly, with no significant issues that compromise its straightforwardness for staff who report their time or for RCP analysts who use the time reporting data.
- **Estimate FTE delta.** The algorithm engine methodology includes data cleaning processes and R scripts to calculate the FTE delta. Key steps are based on easy-to-follow calculations. Understanding the outputs and why unexpected results occur require a deeper understanding of center operations, the algorithm engine's R scripts, and resource capacity planning. FDA plans to move the algorithm engine to the CDEROne platform, which will enable publication of automated dashboards.
- **Adjust FTE delta.** The managerial adjustment consists of four main steps that provide structure to the process and are well documented.

Table B-11. Straightforwardness of CPA Methodology

Evidence of Straightforwardness	PDUFA	BsUFA	GDUFA
Step 1. Forecast workload (submission) volume			
• The transition to univariate and multivariate models alongside generating mechanism models streamlined the methodology and improved its explainability. As a result, analysts have more time to review processes and determine the best approach. Nevertheless, the new models are still complex and require familiarity with statistics, machine learning, and time series models.	✓	✓	✓
• FDA provides training and documentation and pre-built coding libraries (toolkits) in Databricks to explain the models. The machine learning packages used to create the models follow standard methodologies, making it relatively easy for staff to transition from model to model.	✓	✓	✓

Evidence of Straightforwardness	PDUFA	BsUFA	GDUFA
Step 2. Estimate additional FTEs needed for forecasted volume (FTE delta)			
Time reporting data: • FDA's modernized time reporting system (ITR) is straightforward to use and captures data for current direct effort categories (workload drivers) in the CPA methodology.	✓	✓	✓
Time reporting data: • Mapping data from CBER's previous modernized time reporting system, the CBER Activity Time Tracking System (CATTS), to ITR can be challenging for someone not very familiar with the legacy data.	✓		
Time reporting data: • ITR is built on the Salesforce system, which has a reporting structure that allows for effective sharing of information and creation of reports.	✓	✓	✓
Time reporting data: • To maintain clean and consistent data and analysis, most coding changes are implemented at the beginning of a fiscal year.	✓	✓	✓
Algorithm engine: • The algorithm engine methodology is straightforward, well-documented, and ensures work is reproducible and traceable. It is clear how often and when the CPA is run, and what data sources are used.	✓	✓	✓
Algorithm engine: • FDA has ongoing training and documentation efforts to ensure the algorithm engine methodology is clear, accessible, and relatively easy for new staff to learn and implement.	✓	✓	✓
Algorithm engine: • FDA is working toward fully integrating the algorithm engine and workload forecasting in CDEROne. This will make processes more streamlined, faster, more robust, more accessible, and more efficient. Automated publication of dashboards and data outputs will also improve efficiency and accessibility.	✓	✓	✓
Algorithm engine: • Calculation of key variables (unit effort, predicted hours, FTE delta) in the algorithm engine is straightforward.	✓	✓	✓
Algorithm engine: • Methodology updates simplify and improve clarity on which super offices and offices are included in the internal support calculation. A consistent percentage of internal support is applied to each super office and office.	✓	✓	✓

Evidence of Straightforwardness	PDUFA	BsUFA	GDUFA
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)			
• The four main steps of the managerial adjustment (workload forecasting assessment, resource obtainability, adjustment for open and funded positions, other additional factors) provide structure to the process and help make documentation straightforward to follow and understand.	✓	✓	✓

B.1.8 Transparency

ERG evaluated the transparency of the CPA methodology based on the extent to which it approaches steps, calculations, data sources, and rationales are explicitly documented and clearly communicated. We acknowledge that the level of transparency needed for internal purposes (for staff to understand exactly how the methodology works and how to implement it) differs from the level of transparency needed for external purposes (for industry and other interested parties to understand and feel confident in the methodology at a conceptual level). Therefore, we discuss these levels of transparency separately.

Internal Transparency

FDA maintains detailed documentation of the CPA methodology (Table B-12):

- **Step 1. Forecast workload (submission) volume:** *Workload Forecasting as a CPA Input (*updated annually), which provides a comprehensive explanation of forecasting models (including data preparation, models used for each direct effort category, prediction windows, underlying assumptions, evolution of models) for each UFA. PowerPoints also provide details on ongoing efforts, including candidate models to use for future forecasting and a proposed future state with respect to workload forecasting methodology.
- **Step 2. Estimate number of additional FTEs needed to perform forecasted volume of work (FTE delta):** Documents (all updated annually) include those on the methodology and assumptions, standard operating procedures (SOPs), technical design, outputs, and variance analyses for the algorithm engine for each UFA; these documents include recommendations and insights for future enhancements.
- **Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta):** *Managerial Adjustment Internal Memo* (updated annually) for each UFA explains the steps, considerations, and justifications for adjustments made to FTE deltas.

Table B-12. Documents Supporting Internal Transparency of CPA Methodology

CPA Methodology Document	Content
Step 1. Forecast workload (submission) volume	
Workload Forecasting Methodology (updated annually): • Workload Forecasting as a CPA Input	For each UFA, explains workload forecasting process as well as other aspects of resource planning: • Prediction windows • Model selection methodology and evolution of workload models • Generalized modeling approaches • For each submission category, assumptions used, data preparation steps for models, and forecasting models used • Suggestions for possible future enhancements
Step 2. Estimate additional FTEs needed for forecasted workload (FTE delta)	
Methodology documents (updated annually): • CDER PDUFA CPA Methodology and Assumptions • CBER PDUFA CPA Methodology and Assumptions • CDER GDUFA CPA Methodology and Assumptions • CDER BsUFA CPA Methodology and Assumptions	For each UFA, provide detailed explanations of the methodology, including data sources, key assumptions, and how CPA calculations are performed.
SOPs (updated annually): • Algorithm Engine for Capacity Planning Adjustment (CDER): PDUFA, BsUFA, GDUFA SOPs • Algorithm Engine for Capacity Planning Adjustment (CBER): PDUFA SOPs	For each UFA and center, provides step-by-step instructions on how to run the algorithm engine.

CPA Methodology Document	Content
Technical design documents (updated annually): • Algorithm Engine for Capacity Planning Adjustment (CDER) • Algorithm Engine for Capacity Planning Adjustment (CBER)	For each UFA and center, describes the algorithm engines' structure, data fields, scripts, assumptions, and submission categories included in calculations.
Algorithm engine outputs (Excel files, updated annually): • CDER CPA Summary – PDUFA CPA Refresh • CBER CPA Summary – PDUFA CPA Refresh • CDER CPA Summary – GDUFA CPA Refresh • CDER CPA Summary – BsUFA CPA Refresh	For each UFA and center, provides details on data processing and calculations for every step in the algorithm engine.
Variance analyses (updated annually): • Retrospective Variance Analyses - CDER PDUFA • Retrospective Variance Analyses - CBER PDUFA • Retrospective Variance Analyses - CDER GDUFA • Retrospective Variance Analyses - CDER BsUFA	For each UFA and center, provides comparisons of forecasted and actual FTEs, as well as recommendations and insights for improvement.
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)	
Managerial adjustment internal memos (updated annually): • PDUFA Capacity Planning Adjustment: Internal FDA Memo • GDUFA Capacity Planning Adjustment: Internal FDA Memo • BsUFA Capacity Planning Adjustment: Internal FDA Memo	For each UFA, discusses the FTE delta and steps, considerations, and justifications for any managerial adjustments made to the FTE delta.

We evaluated the transparency of these documents used in each of the steps of the CPA methodology, along with other factors that contribute to transparency (Table B-13).

Table B-13. Internal Transparency of CPA Methodology

Evidence of Internal Transparency	PDUFA	BsUFA	GDUFA
Step 1. Forecast workload (submission) volume			
• Workload forecasting is transparent, with clearly defined models and documentation of the methodology. Forecasting models are saved within Lexicon, a centralized system that tracks ownership, allowing model owners to be easily identified and ensuring accountability in model development.	✓	✓	✓
• Changes to the models are tracked in the model scripts and the annual model documentation.	✓	✓	✓
• Steps for refreshing the workload forecast are well defined, reasonable, and account for external factors, such as regulatory changes. o Timeline for refreshing the models is well defined and process is documented. o Data sources are well defined and organized.	✓	✓	✓
Step 2. Estimate additional FTEs needed for forecasted volume (FTE delta)			
Time reporting data: • Centers are transparent about how noncompliance is defined and collect statistics on their level of noncompliance.	✓	✓	✓
Time reporting data: • The time reporting system itself is transparent. A clear record of activities is kept, and users generally agree that ITR categories are well defined and clear.	✓	✓	✓
Time reporting data: • CBER has a definition guide for reporting that is detailed and 50-60 pages in length.	✓		
Time reporting data: • Transparent documentation and available resources lead to a low number of user-specific issues. In FY2024, out of approximately 11,000 ITR users across centers, 36 helpdesk tickets were filed by CBER, and 33 helpdesk tickets were filed by CDER.	✓	✓	✓
Time reporting data: • Reference guides exist for each super office, but they are underutilized, and having clearer reference materials could be useful.	✓	✓	✓
Algorithm engine: • Steps for refreshing the algorithm engine are well defined, reasonable, and documented. o Workload forecasting and time reporting data are the inputs of the algorithm engine. o The model is refreshed in April and October. o Documentation of the technical design, methodology, and SOPs of the CPA are published annually. These annual updates help to simplify and provide clarity on current calculations and practices.	✓	✓	✓

Evidence of Internal Transparency	PDUFA	BsUFA	GDUFA
Algorithm engine: • FDA uses synonyms for some terms without clearly defining that they can be used interchangeably. This hinders the ability for someone not closely familiar with the CPA to follow the methodology and understand the terminology. o These include: Super office/office and office/sub office, submission category and submission type, direct review, direct effort, and workload drivers (similar issue with indirect review), and internal support and support work.	✓	✓	✓
Algorithm engine: • Hours designated as "Multiple" (work that applies to multiple UFAs) and "General" (overhead hours associated with UFA work) are proportionally accounted for, and the distributions are validated.	✓	✓	✓
Algorithm engine: • Methodology updates simplify and improve clarity on which super/sub-offices are included in the internal support calculation. Beginning in FY2024, the methodology to the internal support portion of the resource forecasting algorithms was updated to include all super offices/sub-office direct review workload and applies a consistent percentage of internal support.	✓	✓	✓
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)			
• The four main steps of the managerial adjustment are clearly documented in an annual memo, which follows four main steps including: workload forecasting assessment, resource obtainability, adjustment for open and funded positions, and other additional factors (which can vary from year to year).	✓	✓	✓
• While the intent of the managerial adjustment memos is to keep a record of decisions made regarding the adjustment, to enhance clarity and ensure a reader less familiar with the process (e.g., new staff or future evaluators of the methodology) can follow along more easily, the memo could be edited to improve organization and presentation. For example, it would be helpful to clearly identify each main step and sub-step[7], explain why a main step or sub-step was or was not included, and clearly identify the impact of each main step and sub-step.	✓	✓	✓
• The location and specifics of how to access select data sources mentioned in the managerial adjustment is not always clear. Examples of data sources mentioned with limited context include: an analysis done on rare-disease work, CBER's anticipated submission tracker, and referencing expert/senior leadership's input (but does not specify who specifically is providing input or what the input includes). o Additionally, some terminology is not explained in full detail (e.g., "other BsUFA-specific factors").	✓	✓	

[7] ERG has categorized the main and sub-steps of the PDUFA, BsUFA, and GDUFA managerial adjustments, and the expected impact each main and sub-step has on the delta in the UFA specific workbooks.

External Transparency

Whereas the purpose of internal transparency is to ensure that FDA staff (especially new staff) can understand and implement every detail of the CPA methodology, the purpose of external transparency is to explain the CPA methodology in a way that external parties can understand – so they can judge whether the methodology is sound. FDA provides several publicly available documents and conducts presentations at public meetings for this purpose (Table B-14). Documents provide detailed information on the evolution of the CPA methodology for each UFA, including improvements, steps and components of the methodology, and calculations. The documents clearly communicate the necessary information for an interested party to understand and feel confident in the methodology at a conceptual level. In public meeting presentations, specific examples could be helpful for understanding how the managerial adjustment affects forecasted FTEs. However, FDA can only disclose this information after it has been published in the Federal Register. Nevertheless, FDA could publish the information about the managerial adjustment in the Federal Register when the UFA user fee rates are published, provided space to do so is available.

Table B-14. Documents Supporting External Transparency of CPA Methodology

CPA Methodology Document	Evidence for External Transparency
Federal Register Notices	
Federal Register Notices – PDUFA (published annually since 2021) • Prescription Drug User Fee Rates for Fiscal Year 2025 • Prescription Drug User Fee Rates for Fiscal Year 2024 • Prescription Drug User Fee Rates for Fiscal Year 2023 • Prescription Drug User Fee Rates for Fiscal Year 2022 • Prescription Drug User Fee Rates for Fiscal Year 2021 *Federal Register Notices – GDUFA (published annually)* • Generic Drug User Fee Rates for Fiscal Year 2025 • Generic Drug User Fee Rates for Fiscal Year 2024 *Federal Register Notices- BsUFA (published annually)* • Biosimilar Drug User Fee Rates for Fiscal Year 2025 • Biosimilar Drug User Fee Rates for Fiscal Year 2024 • Biosimilar Drug User Fee Rates for Fiscal Year 2023 • Biosimilar Drug User Fee Rates for Fiscal Year 2022	Annual report for each UFA, provides: • A high-level description of the four steps of the CPA methodology • List of submissions categories included in the CPA and the most recent actual workload volume and forecasted workload volume for each of the submissions categories • Projected FTE delta • Final FY CPA after managerial adjustment

CPA Methodology Document	Evidence for External Transparency
Independent evaluations of the methodology	
Independent evaluations conducted by Booz Allen Hamilton of the proposed UFA CPA methodologies, before implementation • Independent evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology (August 2020) • Independent evaluation of the BsUFA and PDUFA Resource Capacity Planning Adjustment Methodology (April 2020)	For each UFA, provides: • History of CPA methodology • Overview of CPA methodology • Recommendations for improvements of the proposed CPA methodology
FDA RCP and modernized time reporting implementation plans	
FDA update on RCP implementation and modernized time reporting (annual, since 2023I) • Resource Capacity Planning and Modernized Time Reporting Implementation Plan (March 2025) • Resource Capacity Planning and Modernized Time Reporting Implementation Plan (March 2024) • Resource Capacity Planning and Modernized Time Reporting Implementation Plan (March 2023) • Resource Capacity Planning and Modernized Time Reporting Implementation Plan (March 2018)	Annual report that provides: • History of RCP commitments, including those related to the CPA methodology • Update on progress with respect to the RCP commitments, including time reporting and the CPA
FDA public meeting presentations	
FDA public meeting presentations (annual, includes RCP implementation updates) • Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (June 28, 2021) • Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (June 7, 2022) • Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (June 8, 2023) • Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (June 6, 2024)	Annual presentations provide updates on RCP implementation (applies to all UFAs). • The 2021 public meeting describes the algorithm engine development. • The 2022 public meeting presentation includes detailed information on the CPA methodology, including: o An easy to understand overview of how and why workload forecasting is done. o How time reporting hours are used in the forecasted FTE calculation and how it is compared to current capacity. o A description of the four major steps of the managerial adjustment. The 2024 public meeting provides updates on improvements to forecasting models and time reporting data.

B.1.9 Flexibility

ERG evaluated the flexibility of the CPA methodology based on its capacity to account for future changes in workload drivers. We found that (Table B-15):

- Workload (submission) volume forecasting relies on models for each direct effort category (submission type). If an UFA introduces a new category (driver), FDA can develop a model for that category and add it to the CPA methodology reasonably easily. Similarly, FDA's time reporting system can easily accommodate new time reporting codes for new types of work; FDA has added codes in the past when needed (e.g., for COVID-19 pandemic-related work).
- Submission volume and unit effort forecasting is based on historical trends and might not reflect sudden shifts based on sudden changes in drug development priorities, shifts in types (and costs) of expertise needed, events such as the COVID-19 pandemic, and other situations. However, the CPA methodology's managerial adjustment step enables FDA to address such issues, providing sufficient flexibility.

Table B-15. Flexibility of CPA Methodology

Evidence of Flexibility	PDUFA	BsUFA	GDUFA
Step 1. Forecast workload (submission) volume			
• If an UFA adds a new direct effort category (workload driver), FDA can add a model for that category. • Forecasting relies on historical data that do not reflect sudden shifts in unit effort (e.g., changes in the distribution and thus cost of different types of expertise or changes in total hours of work needed per submission type), but FDA can address such shifts in the managerial adjustment.	✓	✓	✓
Step 2. Estimate additional FTEs needed for forecasted workload volume (FTE delta)			
Time reporting data: • FDA can easily add (or delete) time reporting codes based on changes in direct effort categories (workload drivers).	✓	✓	✓
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)			
• The managerial adjustment can address unforeseen changes (not reflected in historical data or current models) that impact resource needs.	✓	✓	✓

B.2 Time Reporting Systems

ERG evaluated the time reporting systems used by FDA staff who perform UFA-related work. We did so by reviewing quantitative data and documentation from FDA and by conducting interviews with FDA staff who manage, use, and work outputs from these systems. This section presents a brief history of time

reporting for the UFAs, followed by strengths and weaknesses of the current system in terms of accuracy, efficiency, user friendliness, flexibility, and technology (Table B-16).

History of Time Reporting for UFAs

Historically, CBER and CDER staff who perform UFA work reported their time for a two-week reporting period every quarter. In modernizing its time reporting system, FDA shifted to a new time reporting system and began requiring time reporting throughout the year (to be completed by the end of each two-week pay period). CDER transitioned from Panorama to ITR in FY2019, before the inception of the CPA methodology. The CBER Activity Time Tracking System (CATTS) was CBER's custom-built, full-time reporting system, implemented in FY2018. CATTS reached its end-of-life, and CBER transitioned to the enterprise wide system, ITR, in FY2024. FDA mapped CATTS time reporting categories to ITR's activity codes to enable the CPA algorithm engine to process both types of data.

ITR provides a unified time reporting system with improved level of detail of data in a centralized platform. Because CBER transitioned to ITR relatively recently, staff are adapting to differences between CATTS and ITR. This is sometimes challenging because ITR was originally designed for CDER's practices and organizational structure. However, ITR also provides a level of customization that allows the centers to adapt the systems to their own needs, mitigating this issue to some extent. CBER time reporting is document-specific. Staff report time for up to 200 activities per pay period, which makes time reporting time-consuming—so time-consuming that ITR sometimes locks out CBER users. In February 2025, FDA introduced a bulk delete button to allow ITR users to delete multiple activities at once, which has helped resolve the lockout issue.

Although ITR does not capture all center-specific nuances in UFA work, it represents a major improvement over previous time reporting systems and practices.

Technology

Built on the Salesforce platform, ITR is a modernized time reporting capability that centralizes data collection across centers and offices—and connects to regulatory submission databases, enabling staff to view submissions assigned to them. CDER has integrated ITR with Databricks (within CDEROne) creating data pipelines for automated reports as well as other time reports and dashboards tailored to individual or office needs. CBER has plans for a similar integration.

Accuracy

ITR is easy to navigate and capable of capturing hours associated with CPA-allowable activities. Automated controls ensure compliance and accuracy by restricting the maximum number of hours users can input per day and sending reminder emails to submit timesheets. FDA managers review the activity codes for which staff report time and work with their staff to make corrections where needed. These controls contribute to a high degree of accuracy of time reporting data. However, staff occasionally underreport their hours due to restrictions on carrying hours from one pay period to another; when they reach the 24-hour credit limit,

they might not recognize the benefit of reporting additional hours. This underreporting is not significant enough to change the CPA.

Cultural and organizational differences across super offices and offices affect timesheet compliance to some extent. Noncompliance tends to be highest during holiday seasons. Nevertheless, ERG's quantitative analysis confirmed that time reporting compliance is consistently above CBER and CDER's 95 percent goal.

Efficiency

ITR has automated links to FDA's regulatory databases, eliminating the need for manual updates; that is, ITR automatically refreshes activity codes for UFA work. For example, when regulatory systems receive a NDA, ITR automatically updates codes to include that NDA with two days. The two-day delay occasionally results in ITR helpdesk requests, but FDA has not found the volume of such requests to be burdensome.

Recording an activity in ITR can sometimes take up to 50 seconds to save. For staff who perform work on numerous activities (such as some CBER staff), this lag can make reporting time-consuming.

User Friendliness

ITR's interface is easy to use, integrates with other tools, and includes helpful features that support a generally positive user experience. Some features include a copy and paste function for activity pathways, a notes section where users can provide additional documentation about tasks, and automatic population of application numbers for assigned users. Additionally, ITR offers staff flexibility for reporting certain types of time. For example, staff can report planned leave up to two pay periods in advance, and can delete activities across multiple pay periods, including with the bulk delete feature. If ITR users struggle to locate an activity code, they can refer to an office-specific guide on SharePoint, consult the frequently asked questions (FAQs), or submit a helpdesk request. ITR users typically receive help within 24-48 hours. In FY2024, CBER staff submitted 36 helpdesk requests and CDER staff submitted 33 helpdesk requests. Given that the total number of ITR users is about 11,000, these small numbers suggest that system-wide issues are minimal.

While CBER users agree that ITR is user-friendly, some would like to restore certain CATTS features—such as marking activities as "favorites" at the office level.

Flexibility

ITR is highly adaptable. For example, within a week of the COVID-19 pandemic, FDA implemented relevant codes to capture new types of work required. In addition, offices can request updates to work category codes. Time reporting staff follow a standard process to review (and implement) potential code changes, usually annually. This maintains consistency within a fiscal year and supports simplicity in coding structures.

Table B-16. Assessment of FDA's Time Reporting System for UFA Work

Evidence	PDUFA	BsUFA	GDUFA
Accuracy			
• ITR is straightforward to use and captures hours associated with work activities in-scope for the CPA. o Users specify the UFA associated with the time reporting activity for it to be accurately recorded in ITR. There are also a number of activities that default to one UFA and therefore do not require the user specifying an UFA. o If work falls in multiple activity categories, FDA encourages "best discretion" in selecting the L1, L2, and L3 hierarchical activity levels in ITR. o Users sometimes need guidance on what activity codes to use for time reporting; users can refer to an office-specific guide, FAQs, or staff or submit a helpdesk request.	✓	✓	✓
• Current data align with historical data, with no persistent errors.	✓	✓	✓
• Centers emphasize the importance of full participation, but compliance enforcement varies by office within each center. Nevertheless, compliance with time reporting requirements (98.06% for CDER, 96.94% for CBER, 97.85% overall) is well above FDA's goal of 95%. CBER's compliance is slightly lower due to its more recent transition to ITR (which was originally designed for CDER's time reporting practices and structures). o Supervisors are responsible for ensuring compliance and have access to a compliance dashboard for this purpose; supervisors decide when and whether to send reminder emails or take other actions in instances of noncompliance. o Noncompliance is somewhat higher during holiday/leave periods.	✓	✓	✓
• FDA has a cap of 24 hours on credit hours (ability to carry over time to the following pay period) per TOD. This can lead to underreporting hours if staff feel no benefit in reporting additional hours after reaching their 24-hour credit limit. This issue is small and does not affect the value of the CPA.	✓	✓	✓
• ITR users who have not reported their time daily receive an email reminder every Tuesday and Friday to complete their time reporting. After a pay period closes, users who have not complied receive a follow-up message on Monday to remind them to complete missing entries.	✓	✓	✓

Evidence	PDUFA	BsUFA	GDUFA
Efficiency			
• Submission data enters the regulatory systems first, then appears in ITR; this refresh process takes two days. If a user inputs an activity code for a new submission that is not yet in ITR, the activity code must be corrected later. This is rarely a problem: in FY2024, only 12 helpdesk requests cited an inability to locate the code for an NDA/BLA number.	✓	✓	✓
• CBER ITR users can balance up to 200 activities in a single pay period, which can be time-consuming because of a lag of up to 50 seconds in saving an activity.	✓		
• CBER users are occasionally locked out of ITR, especially if they work on numerous (>150) activities. In February 2025, a new bulk delete button has helped resolve this issue.	✓		
User friendliness			
• ITR self-populates an activity pathway if a user has been assigned to be a reviewer for a specific submission.	✓	✓	✓
• Users can copy and paste activities and make slight changes.	✓	✓	✓
• Users can mark up to 12 activities as "favorites." This function is used infrequently. CBER staff used this feature more frequently in CATTS, in part because it was available at the branch level.	✓		
• Time reporting using ITR is easier and faster for CDER staff than CBER staff, because CBER code structure entails reporting to the document level. This greater specificity means CBER users have more activity lines to report.	✓	✓	✓
• Users can leave notes of up to 4,000 characters.	✓	✓	✓
• Each office has a list of codes on their SharePoint site. Additionally, users can search for keywords related to codes and find what they need. Of roughly 11,000 ITR users, CBER staff filed only 36 helpdesk requests and CDER staff filed only 33 helpdesk requests in FY2024. Of these, 26 and 16, respectively, cited the inability to locate a specific time reporting code.	✓	✓	✓

Evidence	PDUFA	BsUFA	GDUFA
Flexibility			
• New activity codes can be added quickly when necessary. o Offices can request new codes based on user feedback regarding categorizing work. The time required for a new code to become available can vary; general code updates often take about 3 months. o Urgent requests can be processed expeditiously. For COVID, new codes were available within one week. o For clarity and consistency within a fiscal year, most coding changes are implemented at the beginning of a fiscal year.	✓	✓	✓
• Users can easily delete activities from their timesheets. The recent addition of a bulk delete button has helped users who need to delete numerous activities at a time.	✓	✓	✓
• Users can report planned leave, inspection and training up to two pay periods in advance.	✓	✓	✓
Technology			
• ITR can pull submission numbers directly from regulatory submission databases, eliminating the need to upload information to regulatory and time reporting systems separately.	✓	✓	✓
• Salesforce provides access to all necessary dashboards and reports: o Ability to bypass ITR and create reports. o Reporting folder structure that allows for the effective sharing of information o Utilization, compliance, and time entry reports. o A user can subscribe to up to 12 reports (on average, individual users subscribe to 1-2 reports).	✓	✓	✓
• ITR data pulls are fully automated, occur after each pay period, and are integrated into the CDEROne analytic environment.	✓	✓	✓

B.3 RCP Capabilities for Resource and Operational Decision-Making

Established in 2020, FDA's RCP capability provides information and analyses to support financial planning, resource allocation, and operational decision making. One component of FDA's RCP capability is the CPA methodology. The other component is to provide data and analyses to centers and offices to support resource needs assessments and budgeting and other financial operations. This section presents results for these RCP capabilities, organized by (1) financial planning and management processes, (2) resource needs assessments and related operational decision making processes, (3) overarching RCP strengths, and (4) future considerations. Table B-17 presents an overview of these capabilities.

B.3.1 Financial Planning and Management Processes

FDA's RCP capability supports office-level financial planning and management in several ways. For each UFA, FDA relies on a combination of non-user fee appropriations and user fees. The statute sets a minimum spending from appropriations for reviewing regulated products before accessing user fees. FDA determines this allocation by analyzing process costs—that is, by using time reporting data to define actual time spent on UFA-related activities in CDER and CBER.

Process cost percentages represent the proportion of time spent on process for review of applications as a percentage to total staff reported hours. These percentages, calculated from division to super office level and based on the allowable activities defined in the process for the revie of applications, establish process cost limits, which are the absolute spending ceiling for review activities. Time reporting data for the process cost percentage calculations flow directly from Salesforce into CDEROne with additional validation in Excel. RCP staff calculate process cost percentages and budgetary limits quarterly to support budget execution, financial planning, and operational adjustments.

B.3.2 Resource Needs Assessments and Related Operational Decision-Making Processes

In this section we feature two RCP capabilities that support resource needs assessments and related operational decision making: resource forecasting models and recurring time reports.

Resource Forecasting Models

FDA develops resource forecasting models as tools for constituent offices to leverage forecasting, time reporting, and submission data for the purposes of staffing needs assessments, resource allocation, and operational decision-making. FDA developed its first resource forecasting models in FY2021. Since then, FDA has developed another resource forecasting model and continues to update and improve existing models.

The models serve as directional tools rather than as strict decision-making mechanisms, given that the models cannot capture every factor that affects the use of resources. The outputs of these resource forecasting models help constituent offices with resource and capacity planning, including resource allocation in response to changing workload demand, redistribution of work and related resource implications, and identification of the intersection between resource allocation and organizational strain. The models allow offices to test different scenarios to determine optimal resource allocation. Additionally, the raw submission and time reporting data provides an objective foundation for answering supervisor's

questions, validating claims, calculating unit effort per submission, and potentially making independent decisions in resource planning related to organizational strain.

Users find the models helpful in RCP efforts and continue to work with RCP staff to adapt models for their needs. Some noted that they could benefit from additional training on how to fully utilize all model capabilities and how to further adapt the model to specific needs for their office. For example, staff in one office noted that in future updates it would be helpful if the model could incorporate time reporting information by job type (specifically clinical and project management) and submission type to more dynamically for examine the office's capacity to take on submissions (number of submissions by type).

Recurring and Ad Hoc Time Reports

FDA generates recurring and ad hoc time reports from ITR to help CDER analyze time utilization and resource allocation in relation to the center's mission as well as for other internal management and decision-making tasks. These reports track staff time utilization, compliance, and time entry data. Supervisors rely on utilization reports to identify staff exceeding their TOD requirements, while compliance reports highlight users who might not meet TOD requirements. Separate time entry reports inform FDA staff about the specific activities and categories being recorded. FDA illustrated how ITR staff collaborate with an office supporting the Export Reform and Enhancement Act to analyze time reporting scopes. These reports vary in structure from supervisor-level summaries to center-wide landscape overviews of ITR-reported hours. Users can subscribe to specific reports that cater to center or office goals, and occasionally, custom reports are requested. These requests typically originate from the U.S. Department of Health and Human Services (HHS), the Office of Management and Budget (OMB), or Congress and trigger a refresh of time reporting data. Custom reports provide detailed insights on specific offices, product areas, programs, or sub-programs. These reports, as an RCP output, can reveal and provide evidence in evolving operational decision-making processes.

While CDER allows staff to subscribe to recurring time reports, CBER maintains an annual system that FDA updates after each fiscal year ends. Refreshed reports play a crucial role in financial planning and resource allocation by tracking past and current spending.

B.3.3 Overarching RCP Strengths

FDA's RCP capability includes knowledgeable staff with experience working with a wide range of data, models, tools, and platforms. They apply rigorous approaches to developing, testing, and refining new data-driven models and resources to support resource and operational decision making. They meet with managers and staff in many super offices and offices to ensure a clear understanding of needs and issues—and have demonstrated a willingness and ability to adapt to changes. The RCP staff also communicate 1) the importance of accurate and timely reporting in ITR, and 2) the critical functions and benefits of RCP with supervisors and staff in CDER and CBER offices

RCP staff also maintain strong documentation to ensure that their efforts are transparency and reproducible. Regardless of whether an RCP output is a calculation (process cost percentages), resource forecasting model or recurring time report, well-documented processes ensure an ongoing ability to perform their work and respond to shifting needs. These shifts can be expected or unexpected, such as

adjusting a resource forecasting model based on internal feedback or reflecting a change in submission patterns identified in recurring time reports.

Collectively, RCP outputs are useful for UFA financial management and operational decision making. When planning resource allocations across super offices and offices, decisionmakers can combine historical recurring time reports and resource forecasting models to create a comprehensive strategy.

B.3.4 Future Considerations

As highlighted in the section on RCP strengths, detailed documentation provides for transparency and help facilitate accommodating changes in needs. However, some FDA staff who use RCP outputs do not necessarily have the knowledge or skills to adjust RCP outputs for their specific needs. This knowledge gap is not widespread, but points to a potential need for additional education and training to help FDA staff use RCP outputs for their specific needs or for RCP staff to make adjustments to the outputs as needed.

FDA's RCP staff consider possible improvements to their models and outputs on an ongoing basis. In addition, other offices might benefit from similar resource forecasting models as well. The RCP staff is also working on other modeling initiatives, including developing analytical models and simulation approaches to test opportunities for more efficient and effective regulatory operations, such as managing industry meetings.

In addition to the recommended improvements for the resource forecasting models, RCP staff should continue to provide FDA technology teams with current and future RCP requirements for the new cloud-based initiatives to improve resource planning and workload management across its super offices and offices. CDER has introduced CDEROne, a centralized data analytics platform, and is continuing to move RCP data to this platform. Once completed, this will greatly enhance the efficiency of data analysis which supports RCP work. The implementation of CDEROne will improve the user experience and improve the speed of data processing, resulting in faster model development and data insights. CBER is also working on moving its RCP processes to these platforms, following CDER's model. CDER is also actively developing OneNexus, a centralized workflow management system and user interface that will facilitate and accelerate regulatory review work. OneNexus might be implemented as early as October 2026, serving as an improved user interface to manage workflows and route data to the Document Archiving, Reporting and Regulatory Tracking System (DARRTS) and other repositories. Over time, OneNexus could manage the workflow of the majority of regulatory processes through a single, integrated interface.

Table B-17. RCP Strengths and Future Considerations

Evidence	Process Cost Percentages	Resource Forecasting Models	Recurring and Ad Hoc Time Reports
Overarching strengths			
• Clear instructions and documentation of processes provide clarity in construction of the output and capacity for output to accommodate either expected or unexpected change.	✓	✓	✓
• RCP outputs provide essential insights and guide financial processes and operational decision making in an accurate and data-driven manner.	✓	✓	✓
Future considerations			
• Some RCP output users occasionally do not have the expertise to optimize their use of the outputs. FDA's program office staff using the tools may benefit from additional training or education aimed at using RCP outputs more effectively.		✓	
• RCP resource forecasting models could be expanded by developing similar models for other offices.		✓	
• Continue to provide requirements to FDA technology teams to transition RCP capabilities to the CDEROne platform, with its ability to streamline processes, resulting in faster model development and data insights.	✓	✓	✓

Appendix C. OII GDUFA CPA Methodology Evaluation Results

For GDUFA, FDA currently calculates the CPA based on work performed by CDER. OII also performs work for GDUFA and has developed a CPA methodology for this work. OII and CDER's GDUFA CPA methodologies are structurally and conceptually similar; they differ in specific workload drivers and data sources. When FDA implements the OII methodology, the GDUFA CPA will be the sum of the CDER and OII CPAs. This appendix presents an overview of the OII GDUFA methodology, ERG's assessment of the methodology, and recommendations for improvement.

C.1 Overview of OII GDUFA CPA Methodology

By statute, the GDUFA CPA methodology may include all the workload drivers specified for CDER, plus three types of inspections conducted by OII (Table C-1): Bioresearch Monitoring (BIMO) inspections, Pre-Approval inspections (PAIs), and Surveillance inspections. Two offices in OII perform inspection work: the Office of Bioresearch Monitoring Inspectorate (OBMI) and the Office of Human and Animal Drug Inspectorate (OHADI). The Division of Travel Operations (DTO) supports the travel related to the inspection work. OII has developed a CPA methodology for these drivers but has not yet finalized or implemented it. OII is aiming to implement the methodology for the FY2027 GDUFA CPA; at that time, FDA will likely house the methodology on the CDEROne platform. Figure C-1 through Figure C-4 present the steps in the OII GDUFA CPA methodology.

Table C-1. GDUFA CPA and OII GDUFA Workload Driver Submission and Inspection Category Mapping

GDUFA CPA Workload Driver Submission Categories	OII GDUFA Workload Driver Submission Categories
Abbreviated New Drug Application (ANDA) Originals	BIMO (excluding Analytical) and PAI
ANDA Manufacturing and Labeling Supplements (Prior Approval Supplement (PAS) and Change Being Effected (CBE) Supplements)	BIMO
Controlled Correspondence	
Pre-ANDA Meetings (includes Pre-Submission, Product Development, and Pre-Submission PSG Meetings)	
Surveillance Inspections	Surveillance Inspections
Post-Marketing Safety Activities (PMR/PMC, REMS and Annual Reports)	
Suitability Petitions	

[1] Of the seven workload drivers for the GDUFA CPA, three map to OII inspection categories.

C.2 OII CPA Methodology Steps

Step 1. Forecast workload (inspection) volume

In this step, the OII GDUFA CPA methodology predicts the volume of each type of GDUFA-allowable inspections (Figure C-1). The methodology generates separate forecasts for domestic and foreign inspections (which have different costs) for each inspection type as follows:

- **BIMO Clinical inspections**: Forecast the number of sites that might need inspection during the fiscal year, then divide that number by a conversion factor based on historical FACTS data that reflect how many of the sites might be inspected per year.
- **PAIs:** Forecast the number of ANDAs that might require a PAI during the fiscal year, then divide that number by a conversion factor based on historical FACTS data to determine how many of these might result in a PAI inspection for the CPA year.
- **Surveillance inspections:** Add the annual change in generic drug manufacturing facilities to the current number of generic drug manufacturing facilities and divide that sum by three (because CDER's goal for inspection frequency is every three years).

Step 2. Estimate number of additional FTEs needed to perform forecasted volume of work (FTE delta)

Like the other CPA methodologies, the OII GDUFA CPA methodology estimates the number of additional FTEs needed to perform the forecasted work volume by calculating unit effort and then the FTE delta (for each type of inspection). The calculation of unit effort is more complex because it requires data from two time reporting sources (ITR and FACTS/eNSpect) rather than just ITR. For clarity, we illustrate these steps using two diagrams:

- **Part 1. Calculate unit effort:** Based on historical data, calculate the total number of hours spent on inspections, adjust to include only direct effort hours, and divide that by the number of inspections (Figure C-2).
- **Part 2. Estimate additional FTEs needed (FTE delta):** Multiply unit effort by the forecasted number of inspections from Step 1, convert that number of hours to FTEs, then subtract the number of FTEs currently available (Figure C-3).

As with the other CPA methodologies, the OII GDUFA CPA methodology depends on accurate time reporting data. Historically, OII used FACTS to record time spent on GDUFA inspections. In FY2017, OII replaced FACTS with eNSpect. FDA refers to the system as FACTS/eNSpect because it continues to use historical data from FACTS. As of FY2020, OII now uses a combination of FACTS/eNSpect and ITR:

- FACTS/eNSpect captures all data on inspections, including time reporting for application review, workload management, investigative work, compliance review, analytical operations, quality assurance, and other activities. These hours are linked to specific inspections.
- ITR captures time spent on operational and support activities not represented in eNSpect, including time spent traveling and travel management. These hours are not linked to specific inspections. Note: OII enters inspection time (reported in FACTS/eNSpect) as "Activities reported

in existing OII systems." The OII GDUFA CPA methodology ignores those hours to avoid double counting.

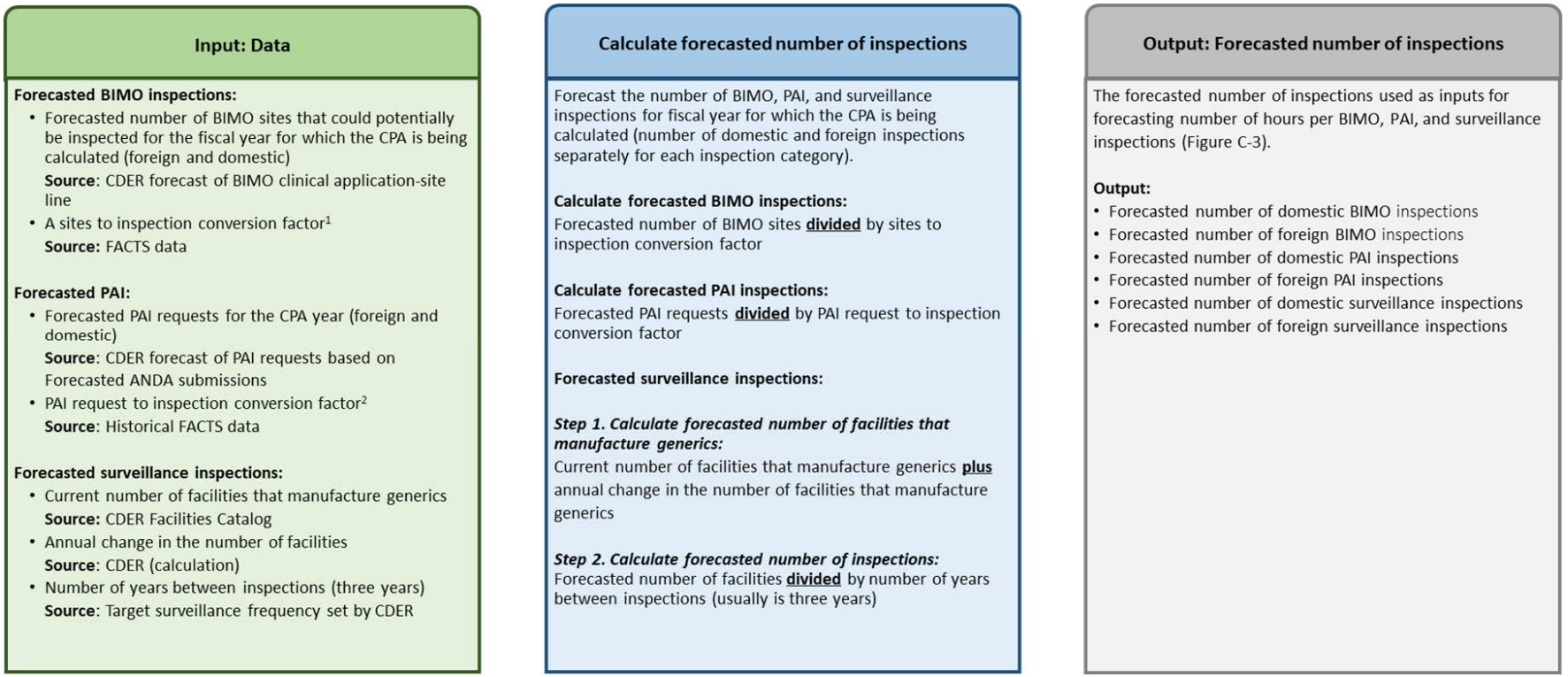
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)

As with the other CPA methodologies, this step (the "managerial adjustment") involves adjusting the FTE delta based on a similar assessment of workload forecasts, funding sources, hiring trends, and the number of new FTEs that FDA can reasonably expect to hire (Figure C-4).

Step 4. Calculate the CPA

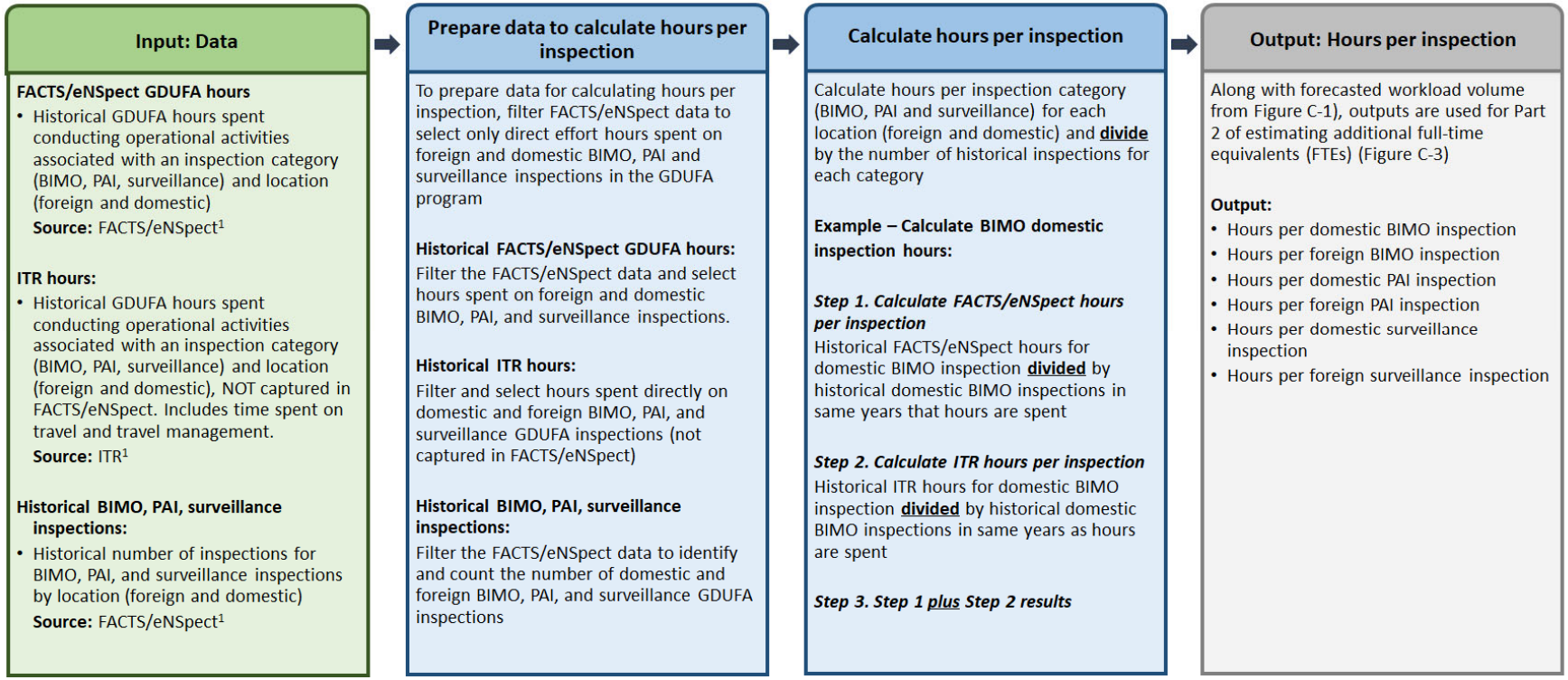
In this step, OII converts the adjusted number of additional FTEs needed to a dollar amount (Figure C-4).

Figure C-1. OII GDUFA CPA Methodology Step 1: FDA's Process for Forecasting Workload Volume



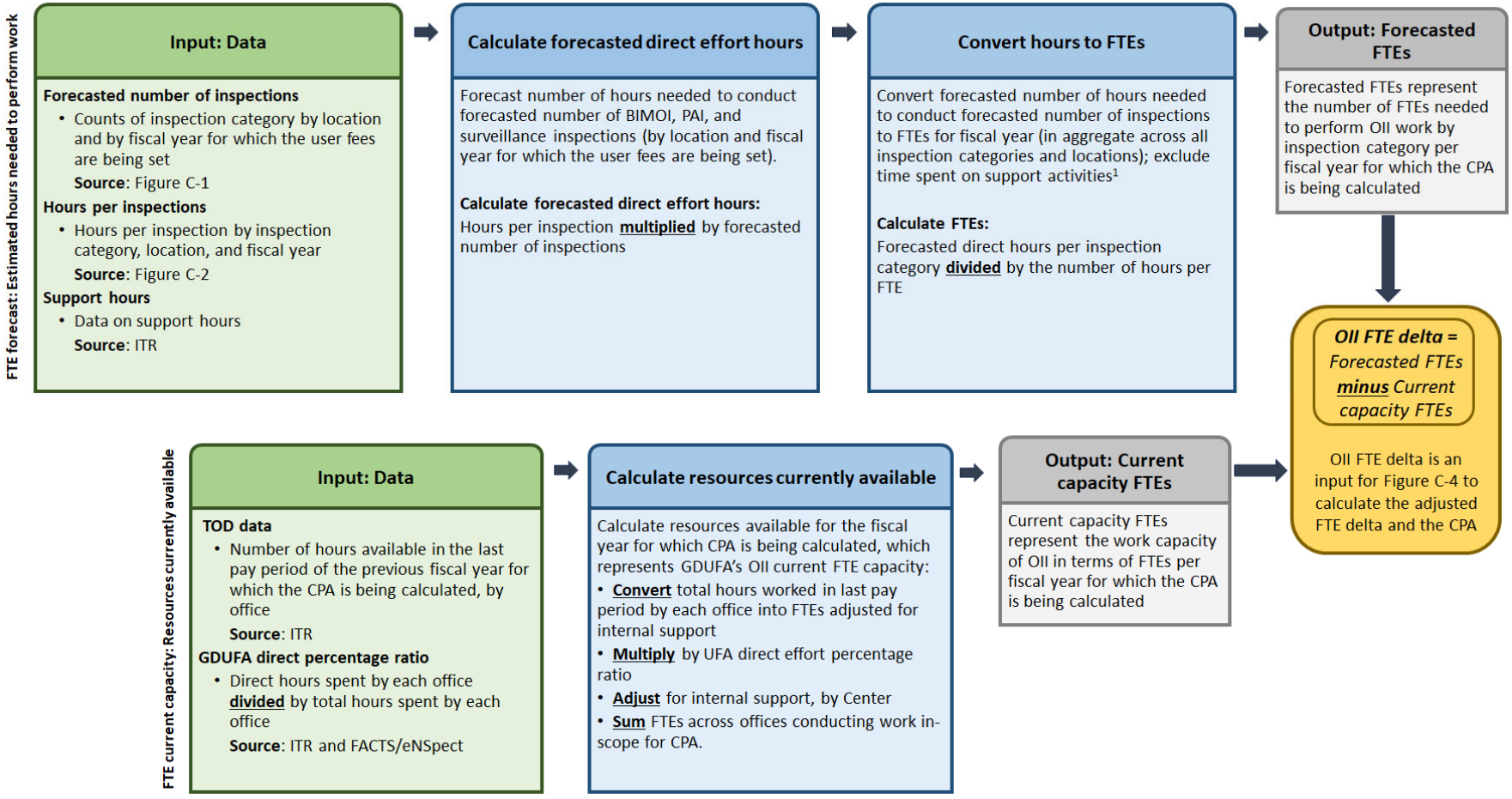
[1] Represents how often a BIMO Clinical application site is inspected.
[2] Represents how often a confirmed PAI request results in an inspection.

Figure C-2. OII GDUFA CPA Methodology Step 2: FDA's Process for Estimating Additional FTEs Needed Part 1: Calculate Unit Effort



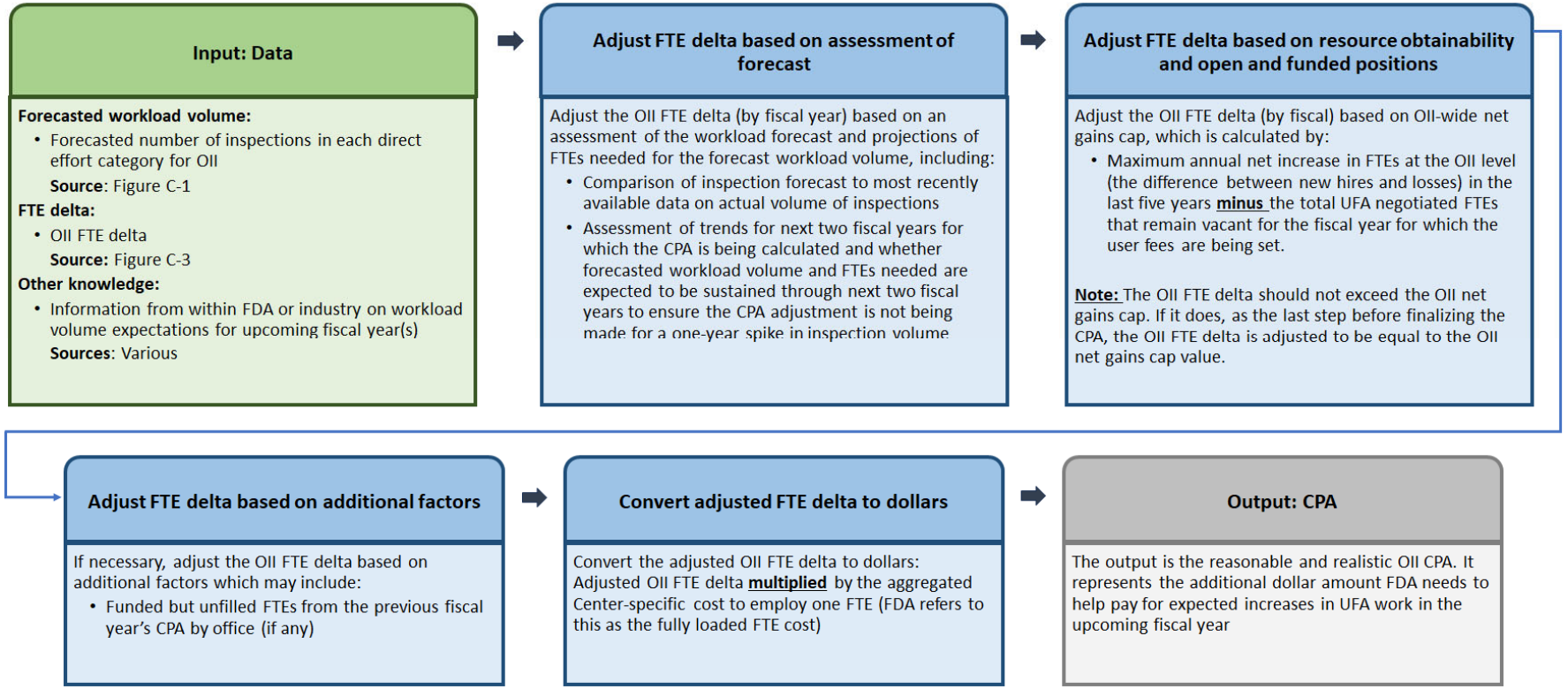
[1] Time periods of historical FACTS/eNSpect and ITR data varies based on available data.

Figure C-3. OII GDUFA CPA Methodology Step 2: FDA's Process for Estimating Additional FTEs Needed Part 2: Estimate Additional FTEs Needed



[1] Support activities include training and professional development, leave, and general and administrative activities.

Figure C-4. OII GDUFA CPA Methodology Steps 3 and 4: FDA's Process to Adjust Estimate of FTE Delta and Calculate CPA



C.2.1 Comparison to CDER GDUFA CPA

In developing the OII GDUFA CPA methodology, OII staff collaborated with CDER to ensure consistency across methodologies. Therefore, the OII GDUFA and the CDER GDUFA CPA methodologies are similar; differences are minor (Table C-2). OII is aiming to implement its portion of the GDUFA CPA methodology for FY2027 fee setting, while CDER GDUFA CPA methodology is fully implemented (as of FY2024).

Table C-2. Comparison of OII GDUFA CPA and CDER GDUFA CPA

Similarities	Differences
Step 1. Forecast workload volume	
• Same structure and conceptual approach to forecasting to workload volume	• Different workload drivers (see Table C-3) • Different data sources • Forecasted by location (domestic versus foreign) in OII due to different cost structures
Step 2. Estimate additional FTEs needed for forecasted workload volume (FTE delta)	
Time reporting data: • Both use ITR for time reporting	*Time reporting data:* • Different time reporting systems (CDER GDUFA uses ITR, OII uses both FACTS/eNSpect and ITR) • Different time reporting practices (CDER GDUFA staff report time for each TOD; OII staff report time when they complete an assignment)
Algorithm engine/CPA Model: • Same structure and conceptual approach to calculating unit effort and additional FTEs needed • Both account for internal support, though use different methods	*Algorithm engine/CPA Model:* • TAP data is not included in OII
Step 3. Adjust estimate of additional FTEs needed (Adjusted FTE delta)	
• Same structure and conceptual approach, involving similar considerations for managerial adjustment (see Figure 3-3 and Figure C-4)	
Step 4. Calculate CPA	
• Same calculation (multiply adjusted FTE delta by cost per FTE)	• Resulting values are different

C.3 Assessment of OII GDUFA CPA Methodology

The OII and CDER GDUFA CPA methodologies are very similar–and so are ERG's assessments of the methodologies (Table C-3).

Accuracy. ERG could not assess the accuracy of the OII GDUFA CPA methodology because FDA has not yet implemented it, so we cannot yet conduct variance analyses.

Breadth. As with the other UFA CPA methodologies, workload drivers in the OII GDUFA CPA methodology are statutorily defined. ERG did not have sufficient data to analyze breadth; we recommend calculating breadth as we did for the other UFA CPA methodologies to determine whether the OII drivers are a reasonable representation of overall OII GDUFA workload.

Defensibility. The OII GDUFA CPA methodology is structurally and conceptually similar to its CDER counterpart. Differences in workload drivers are statutorily defined, and the associated data sources for inspection volumes and unit effort are sound. Similarly, the models and calculations used in the methodology are logical based on the drivers—as are the steps and considerations used in the managerial adjustment. Because OII has not yet finalized its GDUFA CPA methodology, its documentation remains in draft form. Once OII finalizes and implements the methodology, ERG assumes that the office will, like CDER and CBER, conduct performance tests and variance analyses and update a technical design, standard operation procedures, methodology description, and outputs file annually. This will further support the defensibility of the methodology.

Feasibility. Like the CDER GDUFA CPA methodology, OII's methodology uses existing tools and resources—all of which are readily available, accurate, reliable, and sound. Finalizing and updating documentation will benefit any newer staff who need to run the methodology, which further supports feasibility.

Stability. The OII GDUFA CPA methodology mirrors the CDER methodology. Therefore, ERG expects it to have a similar level of stability.

Predictability. The OII GDUFA CPA methodology mirrors the CDER methodology. Therefore, ERG expects it to have a similar level of predictability.

Straightforwardness. The OII GDUFA CPA methodology mirrors the CDER methodology and is therefore similarly straightforward. ERG expects that OII will work toward automating more of the models and calculations over time (as have CDER and CBER for their UFA CPA methodologies).

Transparency. Because the OII GDUFA CPA methodology has not yet been finalized or implemented, its documentation remains in draft form and is less robust (in terms of the number of documents and updates). ERG expects that OII will maintain similar documentation for its methodology to support transparency. Given that OII uses both FACTS/eNSpect and ITR for time reporting, its documentation will

need to clearly delineate these sources and procedures for combining data without double counting hours.

Flexibility. Like the other UFA CPA methodologies, the OII methodology has the flexibility to accommodate changes in workload drivers, time reporting codes, and other changes—and the managerial adjustment provides a mechanism for addressing issues that cannot yet be automated in models.

Table C-3. Assessment of OII GDUFA CPA Methodology by Evaluation Metric

Metrics	Rating[1]	Reason for Rating
Accuracy	No Rating	ERG could not conduct variance analyses because OII has not yet implemented its methodology (which could still change before being finalized).
Breadth	No Rating	ERG is not able to determine if the OII GDUFA CPA methodology accurately captures workload drivers across multiple years because the data to do so was not available. Future analysis to determine breadth may be beneficial.
Defensibility	Very High	Foundational assumptions are sound and largely similar to the CDER GDUFA CPA methodology. • OII GDUFA CPA workload drivers are reasonably and clearly mapped to GDUFA's CPA workload drivers. • Uses accurate, reliable data sources (including time reporting systems). • Managerial adjustment accounts for factors not automated in the models. • When OII implements the methodology, ERG expects that OII will follow many of the same processes and procedures as CDER, including publishing methodology documents annually.
Feasibility	Very High	Uses existing tools and resources; a successful dry run of the methodology also demonstrates feasibility. • Raw data come from established data sources. • Models use well known and reliable programs. • Managerial adjustment relies on available knowledge and resources. • ERG expects that OII will provide training and documentation for staff who need to run the methodology.

Metrics	Rating[1]	Reason for Rating
Stability	Very High	Includes appropriate data and models (for workload forecasting and FTE estimation) and consideration of factors that cannot be automated (in the managerial adjustment). • Uses historical data on submissions, inspections, and hours spent on UFA-allowable activities. • Managerial adjustment can address unexpected or non-automatable factors if necessary. • Accounts for number of FTEs that OII can reasonably hire in a fiscal year.
Predictability	Very High	Uses historical data and accurate time reporting data to support reasonableness of forecasts. • Workload forecasting and unit effort consider historical (actual) data and trends. • Accounts for the number of FTEs that OII can reasonably hire during a fiscal year.
Straightforward-ness	High	Structure and models are as simple as possible given the factors that FDA must take into account in developing a defensible CPA. • Data sources are readily accessible and reasonably straightforward. • ERG expects that OII's implementation will be as standardized and repeatable as the other UFA CPA methodologies. • ERG expects that OII will further automate processes and calculations over time. • Documentation will need to clearly delineate time reporting sources and procedures to avoid double counting hours spent on inspections. • Uses a straightforward approach ensure that funded but vacant positions from the previous fiscal year are not double counted.
Transparency	High	Documentation is sufficient for internal and external transparency. • ERG expects that OII will maintain documentation similar to that for the other UFA CPA methodologies. ERG recommends enhancing the documentation in the same ways we recommend for the other UFA CPA methodologies (see Section 5). • Mapping between CDER and OII GDUFA workload drivers is transparent. • Methodology clearly addresses location (foreign, domestic) of inspections. • Documentation will need to clearly delineate sources and procedures for use of FACTS/eNSpect and ITR time reporting data.

Metrics	Rating[1]	Reason for Rating
Flexibility	Very High	Methodology can add (or delete) workload drivers and time reporting codes or address other changes via the managerial adjustment. • Managerial adjustment considers potential changes in future workload that might not be reflected in historical data. • Managerial adjustment can consider changes in distribution of staff with different expertise/skills (and different cost structures) if needed.

[1] All ratings are subject to change based on changes to the methodology and its implementation.

C.4 Recommendations for Improvement

Time reporting systems

Currently, OII uses a combination of FACTS/eNSpect and ITR data to capture time spent on GDUFA-allowable direct, indirect, and support work. While a single time reporting system would be ideal to for ease of reporting and to maintain time reporting data accuracy and consistency, current technical limitations prevent integration of the FACTS/eNSpect data into ITR. Thus, OII uses FACTS/eNSpect to capture hours spent on investigative and inspectional work (most of OII's activities) and ITR to capture hours spent on activities beyond the inspection (e.g., administrative tasks, time preparing for travel, time spent traveling). While not currently feasible, ERG recommends that FDA remain open to future possibilities to integrate the desired time reporting details from eNSpect into ITR and shifting to a single time reporting system as technology evolves.

Time reporting practices

For any given inspection or investigation assignment, OII staff work in the field for days to months at a time. They generally report their time after completing all aspects of the assignment and returning to the office. Although staff are expected to keep track of their time while in the field, reporting time after an extended period in the field has the potential to lead to inaccuracies in recall. Due to the nature of OII work, time reporting practices must be flexible. To preserve the necessary flexibility while optimizing recall accuracy, FDA provides the ability for OII staff to keep track of time during an assignment. For example, FDA allows staff to input time into eNSpect in draft form and suggest that they record time after completing certain project milestones (e.g., report travel time after returning from travel and before finalizing a written report, then update time after finalizing the report). ERG recommends that FDA use timely reminders or other tools to help users follow these suggested protocols so that time reporting details are recorded as soon as tasks are completed to ensure entries are as accurate as possible.

Appendix D. Text Description of Figures

Figure 1-1: History of FDA's PDUFA, BsUFA, and GDUFA Workload Estimation:

This figure shows the evolution of workload estimation and time reporting practices for the PDUFA, BsUFA, and GDUFA programs over time.

During PDUFA I and II, FDA had absent or partial, incomplete time reporting and no workload adjustments for user fee setting.

During PDUFA II, IV, and V and BsUFA I and GDUFA I, FDA had absent or partial, incomplete time reporting and used the Workload Adjuster to adjust some UFA fees based on submission volume.

During PDUFA VI and VI, BsUFA II and III, and GDUFA II and III, FDA phased in modernized time reporting. FDA used the RCP and CPA methodology to forecast workload and adjust user fees based on submission volume, time reporting data, and other models and adjustments.

Figure 1-2: FDA's CPA Methodology Steps

This figure shows the four main steps in FDA's CPA methodology:

Step 1: Forecast workload (submission) volume: Use forecasting models to predict the volume of workload. This may include regulatory submissions, meetings, and inspections that can be included in the CPA calculation as defined by statute. Note that inspections are included only in the OII GDUFA CPA methodology.

Step 2: Estimate additional FTEs needed for forecasted workload: Based on workload volume forecasts and time reporting data, estimate hours needed to perform work, translate hours into number of FTEs needed, and adjust for FTEs currently available.

Step 3: Adjust estimate of FTEs needed: Analyze reasonableness and feasibility of estimate of FTEs needed and adjust as necessary (FDA calls this the "managerial adjustment).

Step 4: Calculate CPA: Convert adjusted estimate from FTEs to dollars.

Figure 2-1: Evaluation Workbooks

This figure shows three individual evaluation workbooks: the PDUFA Evaluation Workbook, the BsUFA Evaluation Workbook, and the GDUFA Evaluation Workbook. Each of these workbooks contains program-specific observations, analyses and data. All three connect to a central overarching evaluation workbook, which contains key observations and findings. The overlapping areas between each program

workbook and the overarching workbook are labeled "Summary," indicating that analyses from each program are synthesized into high-level results and findings.

Figure 3-1. CPA Methodology Step 1: FDA's Process for Forecasting Workload Volume

This figure shows Step 1 of the CPA methodology, illustrating how FDA forecasts submission volume. This process involves five steps:

Step 1. Input Data: Step 1 is to input the following data elements: *workload volume*, defined as the number of submissions for each direct effort category in UFA program, sourced from FDA regulatory systems; and *explanatory variables,* which are data points intended to explain historical variations in submission volumes for the UFAs and are sourced from internal and external systems.

Step 2: Prepare Data: Filter and select data specific to each direct effort category for the UFA.

Step 3: Run forecasting models: Run models to forecast the number of future submissions for each direct effort category for the UFA. FDA forecasts submission volumes for the next three and a half years to support longer-term planning.

Step 4. Select best forecasts: Use statistical metrics and consider factors such as underlying business expectations and regulatory changes to select the best forecast for number of future submissions for each direct effort category for the UFA.

Output: Forecasted number of submissions: Together, these four steps produce the output: forecasted number of submissions. This includes the forecasted workload volume, defined as the number of submissions, for each direct effort category for the UFA for the fiscal year for which the user fees are being set. These outputs are also used as inputs for estimating resource needs (see Figure 3-2).

Figure 3-2: CPA Methodology Step 2: FDA's Process for Estimating Additional FTEs needed.

This figure illustrates how FDA calculates additional FTEs required to meet workload demands. The process includes two parallel pathways: one to forecast the FTEs needed based on workload, and one to calculate current capacity FTEs. The outputs of both pathways are combined to produce the FTE delta, which is used in CPA calculations.

Pathway 1: Forecasted FTE's Needed (Estimated Hours to Perform Work)

Step 1. Input Data. Step 1 is to input the following data elements**:** *Historical time reporting hours, which represents the t*otal hours spent on a direct effort category for the UFA for the past three years, sourced from Insight Time Reporting (ITR) and CBER Activity Time Tracking System (CATTS); *historical workload volume*, which is the actual number of submissions for each direct effort category for the UFA for the past three years, sourced from the steps described in Figure 3-1; and *forecasted workload volume,*

which is the forecasted number of submissions for each direct effort category for the UFA by fiscal year for which the user fees are being set, sourced from the steps described in Figure 3-1.

Step 2. Prepare Data: Filter and select actual time reporting hours for each direct effort category for the UFA.

Step 3. Calculate forecasted direct effort hours. Step 3 involves calculating forecasted direct effort hours. This includes two calculations: First, calculate unit effort, which is the average number of hours spent on an individual submission in a direct effort category for the UFA. Second, calculate the forecasted direct hours by multiplying the unit effort by the forecasted workload volume for the direct effort category for the UFA.

Step 4. Convert forecasted direct hours to FTEs: Step 4 involves converting the forecasted direct hours to FTEs. This process involves three parts: First, calculate the number of FTEs represented by direct effort hours for the submission category for the UFA by dividing direct effort hours by 2080. Second, calculate the adjusted number of FTEs to account for internal support hours. Internal support includes training and professional development, leave, and general and administrative activities. Finally, roll up office-level values to the super office level.

Pathway 1 Output: Together, these four steps produce the output: forecasted FTEs. Forecasted FTEs represent the number of FTEs needed to perform UFA work by submission category per fiscal year for which the user fees are being set.

Pathway 2: Current Capacity FTE's Resources currently available

Step 1. Input Data: Step 1 is to input three data elements. The first data element is *TOD data*, which represents the number of hours available in the last pay period of the previous fiscal year by UFA and office and is sourced from ITR. The second data element is *planned hiring and expected attrition* which includes two components: the number of planned hires for the UFA for the previous fiscal year for which the user fees are being set and the number of expected staff separated from FDA for the UFA for the previous fiscal year. These are sourced from Talent Acquisition Plan (TAP) data. The third data element is the *UFA direct effort percentage ratio* which is calculated as the three-year average of UFA direct hours divided by total UFA hours for each office, sourced by ITR.

Step 2. Calculate FTEs currently available: Calculate resources available for the year for which the CPA is being calculated, by UFA center, and office, which represents the UFA-specific current FTE capacity. This process follows six steps: First, convert ToD data into FTEs. Second, add the number of planned FTE hires. Third, subtract the number of FTEs from the lost from attrition. Fourth, multiply the result by the UFA direct effort percentage ratio. Fifth, adjust for internal support, by center. Finally, sum the FTEs across offices conducting in-scope work for CPA.

Pathway 2 Output: Together, these two steps produce the output: Current Capacity FTEs. Current Capacity FTEs represent the work capacity of each UFA in terms of FTEs per fiscal year for which the user fees are being set.

FTE Delta Output: At this stage, the forecasted FTEs from Pathway 1 and the current capacity FTEs from Pathway 2 come together to produce the FTE delta. The FTE delta is defined as the forecasted FTEs minus the current capacity FTEs. The FTE delta serves as an input for Figure 3-3 to calculate the CPA.

Figure 3-3: CPA Methodology Steps 3 and 4: FDA's Process to Adjust Estimate of FTE Delta and Calculate CPA

This figure illustrates the CPA methodology, specifically Steps 3 and 4 of FDA's process for adjusting estimates of the FTE delta and calculating the CPA. This process is organized into five steps that begin with inputting data, applying successive adjustments to the FTE delta, converting the result into dollars, and concluding with the output of the CPA:

Step 1: Input Data: Step 1 is to input the following data elements: *Forecasted workload volume*, which represents the forecasted number of submissions in each direct effort category for UFA (by center and office), sourced from the process described in Figure 3-1; FTE Delta for the UFA, FTE delta, sourced from the steps described in Figure 3-2; *actual and forecasted number of FTEs*, which reflect the actual number and forecasted number of FTEs for the UFA from previous years with most recently available actual and forecasted numbers, sourced from the previous CPA and actual data; and other knowledge, which includes information from within FDA or industry on workload volume expectations for the upcoming fiscal year(s) for which the CPA is being set, sourced from internal and external sources.

Step 2: Adjust CPA FTE delta based on assessment of forecast: Step 2 is to adjust the FTE delta for the UFA based on an assessment of the workload forecast and projections of FTEs needed for the forecast workload volume. This includes a comparison of submission volume and FTE forecast to most recently available data on actual volume of submissions. This also includes an assessment of trends for the next two fiscal years for which the user fees are being set to determine whether the forecasted workload volume is expected to be sustained through next two fiscal years and to ensure the CPA adjustment is not being made for a one-year spike in submission volume.

Step 3: Adjust FTE delta based on resource obtainability and open and funded positions: Step 3 involves adjusting the FTE delta based on resource obtainability and open funded positions. For CDER, adjust the FTE delta based on CDER-wide hiring cap, which is calculated by subtracting the maximum annual net increase in FTEs at the center level (the difference between new hires and losses) in the last five years (i.e., net gains cap) by the total UFA-negotiated FTEs that remain vacant for that fiscal year for which the user fees are being set. Note that the FTE delta should not exceed the CBER-wide hiring cap. If it does, as the last step before finalizing the CPA, the FTE delta is adjusted to be equal to the CBER-wide net gains cap value. For CBER, adjust the FTE delta (by office) by subtracting the total UFA negotiated FTEs that remain vacant for that fiscal year for which the user fees are being set. Then compare this to the historical hiring capacity (three-year average and three-year maximum). Note that the FTE delta is adjusted down to account for if hiring capacity exceeds historical hiring capacity.

Step 4: Adjust FTE delta based on additional factors: Step 4 involves adjusting the FTE delta based on additional factors. If necessary, adjust the FTE delta based on additional factors which may include CPA direct review FTEs funded for year for which the user fees are being set, regulatory changes, availability of alternative sources of funding, and subject matter expert and senior leadership input

Step 5: Convert adjusted FTE delta to dollars: Step 5 involves converting the adjusted FTE delta to dollars. This is done by multiplying the adjusted FTE delta by the center-specific aggregated cost to employ one FTE (FDA refers to this as the fully loaded FTE cost).

Together, these five steps produce the output: CPA. Specifically, a reasonable and realistic UFA-specific CPA. It represents the additional dollar amount FDA needs to help pay for expected increases in UFA work in the upcoming fiscal year.

Figure C-1: OII GDUFA CPA Methodology Step 1: FDA's Process for Forecasting Workload Volume

This figure shows Step 1 of OII's CPA methodology for GDUFA, which outlines FDA's process for forecasting workload volume. The process includes gathering input data, calculating forecasted inspection numbers, and producing an output of the forecasted number of inspections:

Step 1: Input Data: Step 1 is to input three data elements. The first data element is *forecasted BIMO Inspections,* which represent the Forecasted number of BIMO sites that could potentially be inspected for the fiscal year for which the CPA is being calculated (foreign and domestic). The first source is the CDER forecast of BIMO clinical application-site line, which includes a site to inspection conversion factor. This factor represents how often a BIMO clinical application site is inspected. The second source is FACTS data. The second data element is *forecasted PAI,* specifically the forecasted PAI requests for the CPA year (foreign and domestic). The first source is the CDER forecast of PAI requests based on Forecasted ANDA submissions, which includes a PAI request to inspection conversion factor. This factor represents how often a confirmed PAI request results in an inspection. The last data element is f*orecasted surveillance inspections,* which captures three components: the current number of facilities that manufacture generics which is sourced from the CDER facilities catalog; the annual change in the number of facilities, sourced from a CDER calculation; and the number of years between inspections (three years), sourced from the target surveillance frequency set by CDER.

Step 2: Calculate forecasted number of inspections: Step 2 involves calculating the forecasted number of BIMO, PAI, and surveillance inspections for the fiscal year for which the CPA is being calculated (number of domestic and foreign inspections separately for each inspection category). This process involves three calculations. First, calculate the forecasted BIMO inspections by dividing the forecasted number of BIMO sites is by the sites to inspection conversion factor. Second, calculate the forecasted PAI inspections by dividing the forecasted PAI requests by the PAI request to inspection conversion factor. Finally, calculate the forecasted surveillance inspections. This calculation is completed in two steps: First, calculate the forecasted number of facilities that manufacture generics, which equals the current number of facilities that manufacture generics plus the annual change in the number of facilities

that manufacture generics. Second, calculate the forecasted number of inspections**,** which equals the forecasted number of facilities divided by the number of years between inspections (usually is three years).

Output: Forecasted number of inspections: Together, these two steps produce the output: forecasted number of inspections. These forecasted number of inspections are then used as inputs for forecasting the number of hours per BIMO, PAI, and surveillance inspections, as shown in Figure C-3. The output includes the forecasted number of domestic BIMO inspections, the forecasted number of foreign BIMO inspections, the forecasted number of domestic PAI inspections, the forecasted number of foreign PAI inspections, the forecasted number of domestic surveillance inspections, and the forecasted number of foreign surveillance inspections.

Figure C-2. OII GDUFA CPA Methodology Step 2: FDA's Process for Estimating Additional FTE's Needed Part 1: Calculate Unit Effort

This figure shows Step 2 of OII's CPA methodology for GDUFA, outlining FDA's process for estimating additional FTEs needed, with Part 1 focused on calculating unit effort. This process is organized into four steps, which begins with input data, then prepares the data to calculate hours per inspection, followed by the calculation of hours per inspection, and concludes with the output of hours per inspection.

Step 1: Input Data. Step 1 is to input the following date elements: *FACTS/eNSpect GDUFA hours,* which represent the historical GDUFA hours spent conducting operational activities associated with an inspection category (BIMO, PAI, surveillance) and location (foreign and domestic), sourced from FACTS/eNSpect; *ITR hours,* which reflects historical GDUFA hours spent conducting operational activities associated with an inspection category (BIMO, PAI, surveillance) and location (foreign and domestic), not captured in FACTS/eNSpect. This includes time spent on travel and travel management and is sourced from ITR; and *historical BIMO, PAI, surveillance inspections*, which identifies the historical number of inspections for BIMO, PAI, and surveillance inspections by location (foreign and domestic), sourced from FACTS/eNSpect. A general note applies to all sources for these inputs: the time periods of historical FACTS/eNSpect and ITR data varies based on available data.

Step 2: Prepare data to calculate hours per inspection: Step 2 involves preparing the data to calculate hours per inspection. To prepare data for calculating hours per inspection, filter FACTS/eNSpect data to select only direct effort hours spent on foreign and domestic BIMO, PAI, and surveillance inspections in the GDUFA program. Each data element undergoes its own filtering process before the hours can be calculated. For h*istorical FACTS/eNSpect GDUFA hours, f*ilter the FACTS/eNSpect data and select hours spent on foreign and domestic BIMO, PAI, and surveillance inspections. For *historical ITR hours*, filter and select hours spent directly on domestic and foreign BIMO, PAI, and surveillance GDUFA inspections (not captured in FACTS eNSpect). For *historical BIMO, PAI, surveillance inspections*, filter the FACTS/eNSpect data to identify and count the number of domestic and foreign BIMO, PAI, and surveillance GDUFA inspections.

Step 3: Calculate hours per inspection: Step 3 involves calculating the hours per inspection category (BIMO, PAI, and surveillance) for each location (foreign and domestic), and dividing that value by the number of historical inspections for each category. For example, calculating BIMO domestic inspection hours follows three steps: First, calculate FACTS/eNSpect hours per inspection by dividing the historical FACTS/eNSpect hours for domestic BIMO inspection by the historical domestic BIMO inspections in the same years that hours are spent. Second, calculate ITR hours per inspection by dividing the historical ITR hours for domestic BIMO inspection by the historical domestic BIMO inspections in the same years as the hours are spent. Finally, sum the results from Step 1 and Step 2.

Together, these three steps produce the output: Hours per inspection. Along with the forecasted workload volume from Figure C-1, outputs are used for Part 2 of estimating additional full-time equivalents (FTEs), referring to Figure C-3. The output includes hours per domestic BIMO inspection, hours per foreign BIMO inspection, hours per domestic PAI inspection, hours per foreign PAI inspection, hours per domestic surveillance inspection, and hours per foreign surveillance inspection.

Figure C-3: OII GDUFA CPA Methodology Step 2: FDA's Process for Estimating Additional FTEs Needed Part 2: Estimate Additional FTEs Needed

This figure shows Step 2 of OII's CPA methodology for GDUFA, outlining FDA's process for estimating additional FTEs needed, with Part 2 focused on estimating additional FTEs needed. The process includes two parallel pathways: one to forecast the FTEs needed to perform work, and one to calculate current resources available. The outputs of both pathways are combined to produce the OII FTE delta, which is used in CPA calculations.

Pathway 1: FTE Forecast: Estimated hours needed to perform work:

Step 1: Input Data: Step 1 is to input the following data elements: *Forecasted number of inspections,* which represent counts of inspection category by location and by fiscal year for which the user fees are being set, sourced from Figure C-1; *hours per Inspection,* which reflects hours per inspection by inspection category, location, and fiscal year, sourced from Figure C-2; and data on *support hours*, sourced from ITR.

Step 2: Calculate forecasted direct effort hours: Step 2 involves calculating the forecasted direct effort hours by forecasting the number of hours needed to conduct the forecasted number of BIMOI, PAI, and surveillance inspections (by location and fiscal year for which the user fees are being set). To calculate forecasted direct effort hours, multiply hours per inspection by forecasted number of inspections.

Step 3: Convert hours to FTEs: Step 3 involves converting the forecasted number of hours needed to conduct a forecasted number of inspections to FTEs for the fiscal year (in aggregate across all inspection categories and locations); exclude time spent on support activities. Support activities include training and professional development, leave, and general and administrative activities. To calculate FTEs, divide the forecasted hours per inspection category by the number of hours per FTE.

Output: Forecasted FTEs: Together, these three steps produce the output: forecasted FTEs. Forecasted FTEs represent the number of FTEs needed to perform OII work by inspection category per fiscal year for which the CPA is being calculated.

Pathway 2: FTE current capacity: Resources currently available

Step 1: Input: Data. Step 1 is to input two data elements. The first data element is *TOD data*, which represent the number of hours available in the last pay period of the previous fiscal year for which the CPA is calculated, by office. This data is sourced from ITR. The second data element is the GDUFA direct percentage ratio, which is calculated by dividing the direct hours spent by each office by the total hours spent by each office. This data is sourced from ITS and FACTS/eNSpect.

Step 2: Calculate resources currently available: Calculate resources available for the fiscal year for which CPA is being calculated, which represents GDUFA's OII current FTE capacity. This calculation involves four steps: First, convert total hours worked in the last pay period by each office into FTEs adjusted for internal support. Second, multiply the result by the UFA direct effort percentage ratio. Third, adjust for internal support. Finally, sum the FTEs across offices conducting work in-scope for the CPA.

Output: Current capacity FTEs: Together, these two steps produce the output: current capacity FTEs. Current capacity FTEs represent the work capacity of OII in terms of FTEs per fiscal year for which the CPA is being calculated.

OII FTE Delta Output: At this stage, the forecasted FTEs from Pathway 1 and the current capacity FTEs from Pathway 2 come together to produce the OII FTE delta. The OII FTE delta is defined as the forecasted FTEs minus the current capacity FTEs. The OII FTE delta serves as an input for Figure C-4 to calculate the adjusted FTE delta and the CPA.

Figure C-4: OII GDUFA CPA Methodology Steps 3 and 4: FDA's Process to Adjust Estimate of FTE Delta and Calculate CPA

This figure shows Steps 3 and 4 of OII's CPA methodology for GDUFA, outlining FDA's process for adjusting the estimate of the FTE delta and calculating the CPA. This process is conducted in five steps:

Step 1. Input Data: Step 1 is to input the following data elements: *forecasted workload volume,* which represents the forecasted number of inspections in each direct effort category for OII and is sourced from the process described in Figure C-1; FTE delta, which is the OII FTE delta that is sourced from the process outlined in Figure C-3, and *other knowledge,* which includes information from within FDA or industry on workload volume expectations for upcoming fiscal year(s). This information is obtained from various sources.

Step 2: Adjust FTE delta based on assessment of forecast. Adjust the OII FTE delta (by fiscal year) based on an assessment of the workload forecast and projections of FTEs needed for the forecast workload

volume, including the following evaluations: One, a comparison of the inspection forecast to most recently available data on actual volume on inspections. Two, an assessment of trends for the next two fiscal year for which the CPA is being calculated and whether the forecasted workload volume and FTEs needed are expected to be sustained through the next two fiscal years. This ensures that the CPA adjustment is not being made for a one-year spike in inspection volume.

Step 3: Adjust FTE delta based on resource obtainability and open and funded positions: Adjust the OII FTE delta (by fiscal) based on the OII-wide net gains cap. The value is calculated by subtracting the maximum annual net increase in FTEs at the OII level (the difference between new hires and losses) in the last five years by the total UFA negotiated FTEs that remain vacant for the fiscal year for which the user fees are being set. Note that the OII FTE delta should not exceed the OII net gains cap. If it does, as the last step before finalizing the CPA, the OII FTE delta is adjusted to be equal to the OII net gains cap value.

Step 4: Adjust FTE delta based on additional factors. If necessary, adjust the OII FTE delta based on additional factors which may include funded but unfilled FTEs from the previous year's CPA by office (if any).

Step 5: Convert adjusted FTE delta to dollars. Convert the adjusted OII FTE delta to dollars by multiplying the adjusted OII FTE delta by the aggregated Center-specific cost to employ one FTE (FDA refers to this as the fully loaded FTE cost).

Output: CPA: Together, these five steps produce the output: CPA. Specifically, a reasonable and realistic OII CPA. It represents the additional dollar amount FDA needs to help pay for expected increases in UFA work in the upcoming fiscal year.