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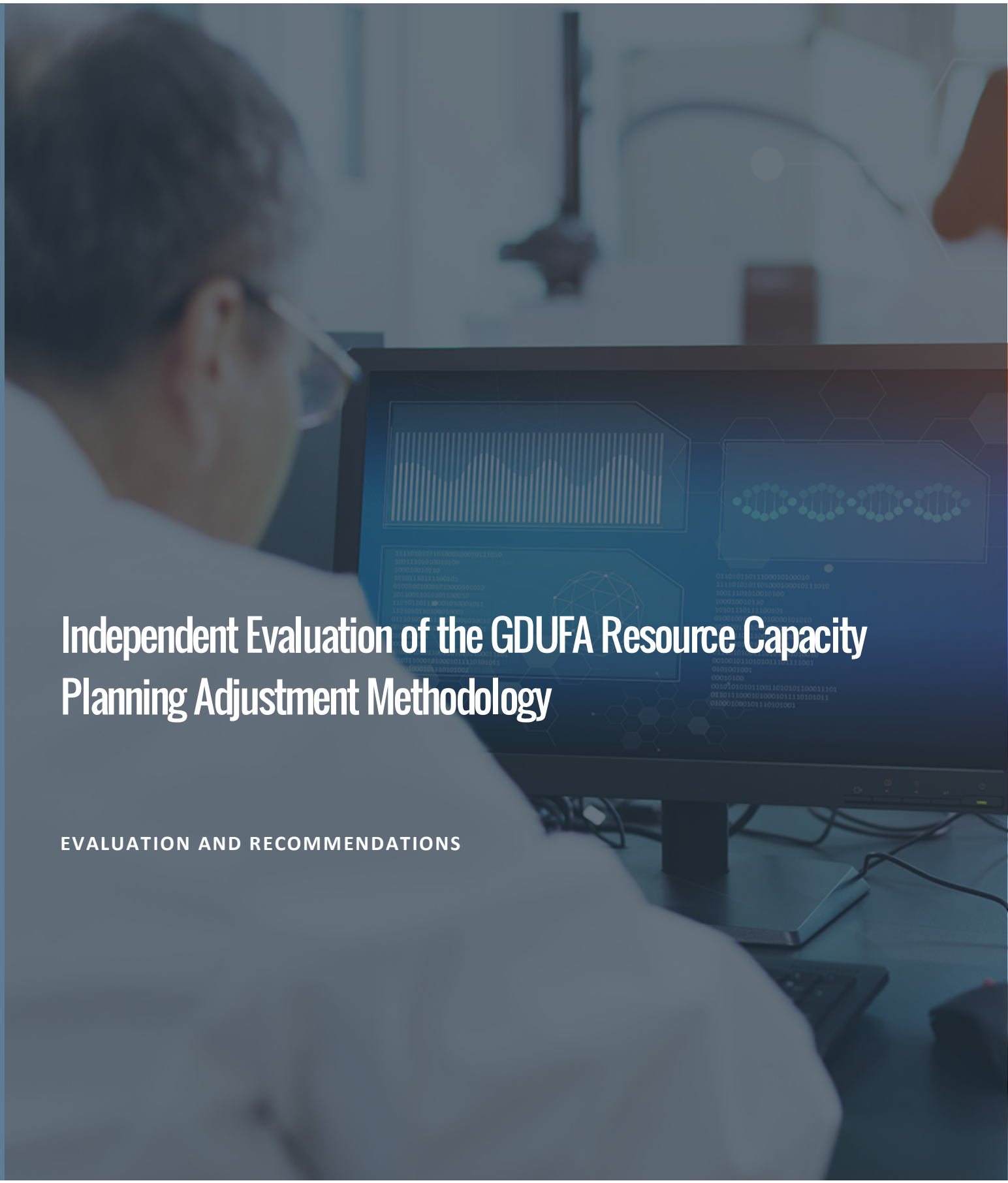

Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology

EVALUATION AND RECOMMENDATIONS

CONSULTING | ANALYTICS | DIGITAL SOLUTIONS | ENGINEERING | CYBER

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EXECUTIVE SUMMARY

As part of the FDA Reauthorization Act of 2017 (FDARA), Booz Allen evaluated the Food and Drug Administration's (FDA) proposed Capacity Planning Adjustment (CPA) methodology that annually adjusts the target revenue within a user fee program to account for additional resource needs due to a sustained increase in workload. The report examines if the proposed CPA methodology could be applied to the Generic Drug User Fee Amendments (GDUFA) program and meet the monitoring and reporting of resource needs of the program. It also provides options and recommendations for the proposed CPA methodology should the GDUFA program decide to implement the adjustment.

The FDARA includes provisions for an independent assessment of FDA's CPA methodology.[1] As the independent assessor, Booz Allen utilized a hypothesis-driven evaluation framework to evaluate the proposed CPA methodology based on appropriate criteria for forecasting methodologies. Specifically, Booz Allen evaluated whether FDA's conceptual framework with the proposed CPA methodology could be leveraged for the GDUFA program to accurately assess, monitor, and report on changes in resource and capacity needs.

As part of the GDUFA II Commitment Letter, FDA agreed to develop a resource capacity planning (RCP) function and modernized time reporting (MTR) approach that enhances the management of user fee resources.[2] FDA has created a proposed CPA methodology to reflect changes in the resource capacity needs for the GDUFA program. At a high level, this process would start with calculating the workload forecast to estimate the volume by types of submissions. FDA would then calculate the resource demand forecast for direct review-related effort using time reporting data. With the output of the workload and resource demand forecasts, which the models convert to Full-Time Equivalent (FTE) counts, FDA would apply a managerial adjustment to ensure the CPA adjusts only for new resources that cannot be supported through existing funds. Using the final FTE value from the managerial adjustment, FDA would subsequently convert FTEs to dollars. FDA would then add the resulting value to the annual target revenues for the GDUFA program accordingly.

FDA provided Booz Allen with all relevant CPA methodology materials, time with FDA staff to conduct stakeholder interviews and targeted discussions, and regular Technical Advisory Group (TAG) feedback to validate program-wide objectives and methodology design considerations. After evaluating all the data collected through the hypothesis-driven framework, Booz Allen developed findings based on the proposed CPA methodology's relationship to the definition of each evaluation criteria. Evaluation criteria and hypotheses align up to an overarching hypothesis that the proposed CPA methodology could be applied to the GDUFA program and meets the monitoring and reporting of resource needs. Overall, FDA's proposed CPA methodology would align with the objective to develop a methodology that accounts for the sustained increases in the GDUFA program resource needs to perform reviews. The summary of evaluation findings describes the extent to which FDA's proposed CPA methodology addresses each of the evaluation criteria as of the submission of this report. Booz Allen also developed accompanying recommendations for the proposed CPA methodology that FDA may consider should it choose to implement a CPA for the GDUFA program. Table 1 provides a high-level summary of the evaluation findings by each evaluation criteria.

[1] FDA Reauthorization Act of 2017 (FDARA). Retrieved from https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf.
[2] GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter). Retrieved from https://www.fda.gov/media/101052/download.

Table 1: Summary of Evaluation Findings

Evaluation Criteria	Definition	Finding Summary
Accurate	The methodology comprehensively includes workload submission types in a manner that will likely forecast resource demands close to real world figures (e.g., submission volume).	The proposed CPA methodology for the GDUFA program would use a data-driven approach to predict the likely submission volume FDA will receive as part of the direct review workload. These predicted submission volumes would then be used to estimate resource needs for the GDUFA program with the use of time reporting data. As the proposed CPA methodology would capture major drivers of workload within the GDUFA program, FDA needs to explore all types of work that should be considered as direct review work and include them in the proposed CPA methodology to calculate accurate resource needs.
Adaptable	The methodology can be scaled up as data and environment grow, expand, and change with new and evolving business needs.	The proposed CPA methodology could adapt and account for a variety of data sources that may support the prediction of workload levels and resources needs of the GDUFA program. This methodology would utilize open-source software (OSS) with R and Python that gives the flexibility of incorporating various data formats. The managerial adjustment process would allow FDA to account for future business needs in the GDUFA program that may impact the CPA process. The methodology could act as a tool for the GDUFA program to use outside of fee setting for monitoring and reporting resource needs.
Defensible	The objectives, inputs, mechanism, rationales, and expected outputs of the methodology are clearly defined. Methods and expected outputs are compatible with specified requirements.	The proposed CPA methodology would align to requirements set forth in the GDUFA II Commitment Letter. The overall CPA methodology and model development process are based on assumptions that FDA expects to remain true over time in the GDUFA program.
Efficient	The methodology can be maintained in a manner that maximizes benefits, optimizes resources, and minimizes effort.	FDA could use existing technology for forecasting and customize it to the unique challenges that are relevant in accurately estimating the upcoming workload level and resource needs of the GDUFA program. The use of the proposed CPA methodology for the GDUFA program could leverage a similar process used in the Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Amendments (BsUFA) programs that report resource needs to the industry stakeholders for promoting efficiency and consistency.
Feasible	The methodology can be implemented as planned and can be replicated and maintained in future years.	Based on FDA's ability to build the initial set of workload forecast models and the availability of time reporting data that could be used to build the resource demand forecast models, there is evidence that FDA has the tools and data sources available to begin the implementation of the proposed CPA methodology in the GDUFA program. However, there are some offices outside Center for Drug Evaluation and Research (CDER) that currently support GDUFA activities but do not record time. These offices are expected to report their time in the future as a result of the MTR implementation.
Meaningful	Expected methodology outputs are relevant and valid to the questions they are informing and are understood and accepted by decision-makers.	FDA is developing and validating a managerial adjustment process within the proposed CPA methodology for the PDUFA and BsUFA programs. This approach will potentially look at factors of accuracy of previous years' forecasts, whether forecast resource needs are sustained over the next three years, hiring and attrition rate trends, and availability of other sources of funding. These factors could similarly be applied to the GDUFA program once finalized.

Overall, FDA's proposed CPA methodology would align conceptually with the plans to develop a methodology that accounts for the changes in resource needs from the sustained increases in GDUFA program workload. If the proposed CPA methodology is adopted, further developed, and iterated on for the GDUFA program, Booz Allen created a set of recommendations that would provide FDA

with opportunities to further accurately assess the additional resource needs and report on these needs. Table 2 provides a high-level description and alignment of recommendations to the relevant evaluation criteria.

Table 2: Summary of Recommendations

Recommendation	Relevant Evaluation Criteria
Related Direct-Review Work: FDA should perform data exploration that analyzes how to incorporate all types of review-related work into the workload and resource demand forecast models that are applicable for the proposed CPA methodology determined by the GDUFA program. FDA should continue exploring and capturing the resource needs for direct review workload types of Abbreviated New Drug Application (ANDA) Originals, ANDA Original Resubmission / Amendments, ANDA Supplements, ANDA Supplement Resubmission / Amendments, and Controlled Correspondences. FDA could further consider capturing resource needs for the workload associated with 1) post-approval and pre-ANDA submission work that include submission types related to post-market safety and surveillance, policy and guidance development, the GDUFA II Pre-ANDA program, Pre-Submission Facility Correspondence (PFC), requests for Combination Product Agreement Meetings (CPAM), method validation program, and dispute resolutions; and 2) submissions that have an internal review performance goal but no performance metric goal within the GDUFA II Commitment Letter and, subsequently, no required timeline for review. FDA may want to implement the models at the appropriate level of detail for each of the direct review workload types, prior to breaking out these models into distinct characteristics of each submission type.	Accurate Feasible Meaningful
Modernized Time Reporting Formal Implementation Plan: FDA should create a formal implementation plan for adding the capabilities of MTR in each of the remaining offices that perform direct review workload activities within the GDUFA program but currently do not have a formal plan yet created.	Accurate Defensible
Managerial Adjustment Process Development: FDA could refine the managerial adjustment process for the GDUFA program with additional steps and data to help make informed decisions by: 1) evaluating the accuracy of adjustments made in the previous fiscal years' managerial adjustment process, 2) exploring the development of business scenarios to be included in the managerial adjustment process in future years, and 3) generating hiring metrics that outline how long it takes on average to hire new FTEs by job role and discipline.	Adaptable Meaningful
Reporting of Resource Needs: FDA should follow a similar process used by the PDUFA and BsUFA programs for the GDUFA program to monitor and report the resource needs by utilizing 1) the Generic Drug User Fee Rates Federal Register Notice, 2) the annual financial reports, and 3) the five-year financial plans.	Adaptable Efficient Meaningful
Evaluation of Time Reporting Data Collection Process: Once FDA finalizes the types of direct review workload that will be included in the proposed CPA methodology for the GDUFA program, FDA should evaluate the structure of the time reporting categories associated with each of the direct review workload types to ensure it is optimally designed to accurately predict resource needs.	Accurate Feasible
Prediction Intervals: FDA may consider whether creating prediction intervals for the resource demand forecasts would add practical value for the decision-makers in the managerial adjustment process to assess the future uncertainty in the mean estimates and make relative adjustments.	Accurate Meaningful
Model Interpretability: FDA may consider whether increasing interpretability within the complex models used in advanced analytical techniques for workload forecasting would help inform the managerial adjustment process by providing insights as to why the models are estimating specific number of submissions.	Accurate Meaningful
Methodology Documentation: If the proposed CPA methodology does become a requirement as part of the GDUFA program target revenue fee adjustments, FDA should consider developing the overall methodology assumptions, rationales, and procedures in the technical appendices and related documentation to provide a baseline as the methodology evolves over time.	Adaptable Defensible Efficient

1 INTRODUCTION

FDA developed a new CPA methodology through authority given by FDARA that can account for sustained increases in workload. FDA contracted Booz Allen to conduct an assessment focused on evaluating whether FDA's proposed CPA methodology for determining the resource needs could apply to the GDUFA program. This section provides an overview of the project background and objectives of assessment.

1.1 Background

FDA is responsible for protecting and promoting public health by ensuring that patients and providers have timely and continued access to safe, effective, and high-quality medical products.[3] Specifically, FDA has the regulatory authority over human and veterinary drugs, biologic products, and medical devices. FDA also has the responsibility to regulate manufacturing, marketing, and distribution of tobacco products while ensuring the safety of the U.S. food supply, cosmetics, and products that emit radiation. Each year, FDA reviews thousands of submissions to ensure that medical products are both safe and effective prior to entering the market. Congress authorizes funding as an annual appropriation so that FDA can perform its responsibilities.

In order to ensure that patients have continued access to safe, high quality and affordable drugs, Congress enacted the GDUFA in 2012. These amendments ratified an agreement negotiated by the generic pharmaceutical industry (industry) and the agency and enabled FDA to assess industry user fees in order to provide improved predictability and timeliness to the regulatory review process of generic drug applications. The continued authorization of this authority aims to provide a firm financial avenue for FDA's generic drug program through the assessment of user fees to fund critical and measurable enhancements over the next five years. Moreover, FDA spends GDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for generic drug activities.

In its second authorization, the GDUFA program faces an increasing workload as it continues to mature. For example, GDUFA I workload projections were based on the assumption that FDA would receive 750 ANDAs each year. However, approximately 1,000 ANDAs were received each year. The GDUFA II assumed an increased number of submissions to 1,000 ANDAs annually, as well as more aggressive review timeframes. Increased post-approval review efforts are also resulting from increased approvals of generic drug applications. While GDUFA II accounts for a higher workload, submission volatility could continue that may require additional resource needs.

Along with a higher workload, GDUFA II must account for program enhancements and possible changes in trends in the generic drug industry. Enhancements include improved development and review of hard-to-genericize complex products, streamlined business processes to increase first cycle approvals, reduced timeframes for approvals with increased communication and collaboration with the generic drug industry, and providing additional support to applicants in ANDA preparations through a pre-ANDA program.

Under GDUFA II, FDA is required to develop a plan that establishes an RCP function and to modernize its time reporting functions. FDA must also improve efficiency and transparency in the administration of the GDUFA financial resources. FDA committed to a third-party evaluation to identify options and provide recommendations to accurately assess changes in resource demands and how to monitor and report on these needs in the future.

1.2 Objectives

The key objectives of this evaluation include:

- Evaluate if FDA's proposed CPA methodology that assesses the workload level and resource needs of a user fee program could be applied to the GDUFA program
- Determine if FDA's proposed CPA methodology could be used to monitor and report on resource needs for the GDUFA program
- Provide options and recommendations that could feasibly improve the proposed CPA methodology

[3] The Federal Food, Drug, and Cosmetic Act (FD&C Act). Retrieved from https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act.

2 FDA CAPACITY PLANNING ADJUSTMENT METHODOLOGY OVERVIEW

Currently, the GDUFA program employs a two-step process to set the target revenue for each fiscal year and does not include an adjuster for capacity planning. The intent of the proposed CPA methodology would be to account for changes in resource needs if there is sustained increase in workload for the generic drug programs. FDA is evaluating if the conceptual framework of the proposed CPA process could be applied to the GDUFA program.

2.1 Introduction to Capacity Planning Adjustment

The target revenue methodology is an annual process defined in statute, 744B(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), to calculate the target revenue for the GDUFA program for the following fiscal year.[4] FDA's current method uses the yearly revenue from the prior fiscal year as a starting point and then applies an inflation adjustment across the program, which involves multiplying the previous year's revenue amount by the inflation percentage to get the next year's target revenue. The resulting target revenue amount is used to establish the various fees across the GDUFA program.

Currently, the GDUFA program is not required to apply additional adjustments in its target revenue calculations other than inflation.[5] However, the CPA is an adjustment that could be applied to the GDUFA program during the target revenue process. The purpose of the CPA is to modify the base revenue for the GDUFA program to reflect the changes in resource needs for application reviews. The adjustments from the proposed CPA methodology would be applied once FDA applies the inflation adjustment. Figure 2-1 illustrates the GDUFA annual target revenue methodology inclusive of a CPA, to provide context as to how the proposed adjustment would be integrated into the overall process.

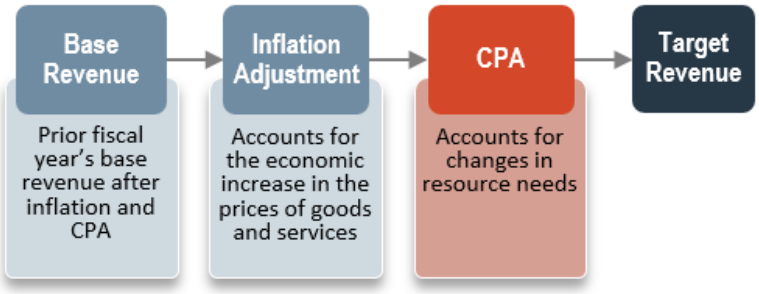

Figure 2-1: Illustrative GDUFA Target Revenue Methodology with CPA

The section below discusses the key steps used to calculate the CPA factor that FDA could apply to the annual target revenue. To help further understand the proposed CPA methodology, Table 2-1 provides a description of key concepts that are important for understanding the CPA methodology.

[4] Generic Drug User Fee Rates for Fiscal Year 2020. Retrieved from https://www.federalregister.gov/documents/2019/07/26/2019-15906/generic-drug-user-fee-rates-for-fiscal-year-2020.

[5] There is also a final year adjustment, defined in statute 744B(2) of the FD&C Act, to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of fiscal year 2023.

Table 2-1: Key CPA Concepts

Concept	Description
Direct Review Work	Work that would be directly related to the review of types of submissions under the GDUFA program and considered in-scope for the CPA methodology
Indirect Review Work	Work that would support review and other regulatory work related to the GDUFA program, but not within scope of direct review work and the CPA methodology
Internal Support Work	Work that would be related to the lifecycle of an employee in the GDUFA program such as training, professional development, leave, and administrative activities, but not inside the scope of direct or indirect review work
Workload	Amount of submission volume that FDA would receive within the GDUFA program
Resource Demand	Number of FTEs that would be required to support the workload in the GDUFA program, including both direct review and internal support
Capacity	Estimated available allocated hours among all the existing resources for the GDUFA program
CPA Factor	Output of the CPA process that is applied to the inflation-adjusted base revenue, per the target revenue adjustment methodology, which accounts for the additional user fee funds FDA would need to support an increase in workload in the GDUFA program

2.2 Proposed Capacity Planning Adjustment Methodology

FDA is proposing a CPA methodology to account for additional resource needs due to increases in workload and is testing whether this conceptual methodology could be applied and tailored to the GDUFA program. To do so, FDA would determine which of the direct review workload types are applicable in the CPA process for the GDUFA program to build the workload and resource demand forecast models. The proposed CPA methodology would use a four-step structured and data-driven process to calculate the adjustment factor as outlined in Figure 2-2. This factor would then be included as an adjustment in the target revenue methodology.

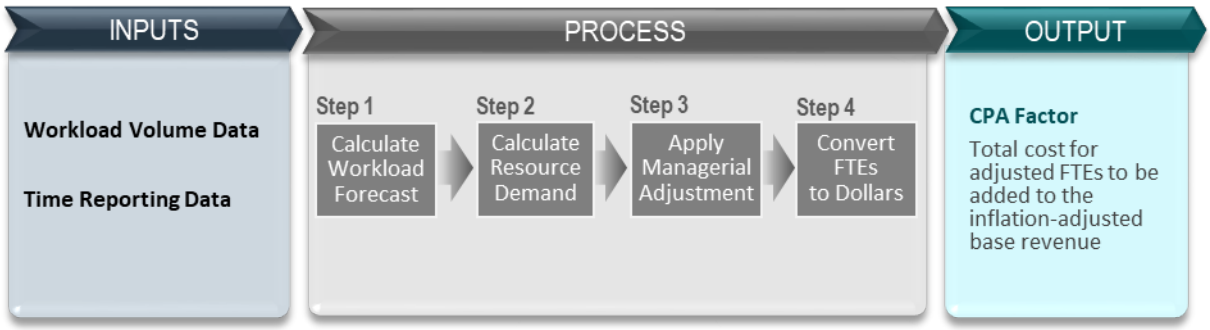

Figure 2-2: Proposed GDUFA CPA Methodology Overview

The following sections describe each step of the process used within the proposed CPA methodology at a high level.

Step 1: Calculate Workload Forecast

The first step of the proposed CPA methodology would be to estimate the submission volume that will likely be received for the direct review workload types for the upcoming 3.5 fiscal years within the GDUFA program. FDA will generate these estimates using advanced analytics techniques through statistical analysis and machine learning that will help inform the workload levels FDA should expect in the upcoming fiscal years.[6]

Step 2: Calculate Resource Demand Forecast

The second step of the proposed CPA process would be to calculate the resource demand estimates for the upcoming workload associated with the direct review workload types. FDA would calculate the resource demand estimate by converting the forecasted submission volume from Step 1 into resource needs measured by FTEs. FDA would analyze the historical time reporting and submission

[6] Statistical analysis is the science of data collection and exploration that identify trends and patterns. Machine learning applies artificial intelligence to teach systems to improve outputs through the application of experience.

volume data to gain a macro-level view of the level of effort required for each of the direct review workload types. Additionally, the forecast for the resource needs involved in the direct review work would also consider internal support work for activities related to training and professional development, leave, and administrative duties. This is to account for the full lifecycle of an employee's roles and responsibilities. Once FDA calculates the forecasted FTE needs for the GDUFA program, a difference would be determined between the estimated resource demand and current capacity within the program to understand the number of additional FTEs required to meet the projected future submission workload.

Step 3: Apply Managerial Adjustment

The third step of the proposed CPA process would be to engage in an internal structured decision process through managerial adjustments. This decision process would ensure that any fee adjustment made only reflects what could be reasonably and realistically used to support the GDUFA program. FDA would consider factors such as how the forecasts compare to the actuals from the previous fiscal year, whether the forecasted changes are sustained, whether the additional resources capacity can be hired in a timely manner, and if there are other available funds to allocate for the resource needs. Based on this structured decision process, FDA may make an adjustment to the resource demand FTE counts derived in Step 2 for the GDUFA program.

Step 4: Convert FTEs to Dollars

The fourth step of the proposed CPA process would be to calculate the total cost associated with the adjusted FTE count. FDA has a fully loaded FTE cost model that factors in pay, non-pay, and rent costs associated with employees. FDA would use this cost model to calculate a total cost by multiplying the adjusted total FTE count and overall cost per employee. FDA would then add this cost to the inflation-adjusted base revenue of the user fee program for reflecting the changes in resource capacity needs for the process of application reviews in the GDUFA program.

3 EVALUATION FRAMEWORK

Booz Allen employed a hypothesis-driven approach to evaluate if the proposed CPA methodology could be adopted by the GDUFA program to assess, monitor, and report on FDA's resource needs with the end goal of developing a detailed report outlining findings. Multiple sources of data that include methodology documentation, interviews, statutes, and reports contributed to the analysis and development of recommendations for consideration as FDA looks to potentially implement the methodology in the GDUFA program.

3.1 Evaluation Framework

Booz Allen created an evaluation framework that used a hypothesis-driven approach to ensure a structured and systematic analysis to accomplish the key objectives of the assessment. Given the exploratory nature of this evaluation, we performed a conceptual review of the proposed CPA methodology that did not include running data analysis on the models. However, Booz Allen conducted a review of technical documentation on the approach that FDA has taken for initial model development, inclusive of the potential performance of the models and associated outputs. To accomplish the goals of the assessment, Booz Allen's evaluation framework used a hypothesis-driven approach to ensure a structured and systematic analysis of the proposed CPA methodology. Overall, the evaluation consisted of providing options and recommendations to FDA on how to further accurately assess the additional resource needs and report on these needs if the proposed CPA methodology was adopted, further developed, and iterated on for the GDUFA program. To align with documentation and forecasting practices, the hypotheses center around two concepts: applicability of CPA methodology and evaluation criteria. These two concepts are described further below.

Applicability of CPA Methodology

Booz Allen assessed if the conceptual framework of the proposed CPA methodology could be applied to the GDUFA program, which is a similar methodology being proposed for the PDUFA and BsUFA programs. The evaluation analyzed if there are any unique requirements in the GDUFA program that would require modifications to the conceptual framework of the proposed

CPA methodology. We also analyzed if the outputs generated by proposed CPA methodology would meet the monitoring and reporting of the resource needs in the GDUFA program.

Evaluation Criteria

Booz Allen developed hypotheses based on six different evaluation criteria across the capacity adjustment process to drive our approach in assessing the potential effectiveness of the capacity adjustment process should it be adopted by the GDUFA program. This approach allowed us to assess the CPA methodology against industry-accepted qualities. Booz Allen selected criteria that were relevant and realistic ways of assessing the proposed CPA methodology for the GDUFA program. The development of definitions for each evaluation criteria accounted for a conceptual-level evaluation of the CPA. Table 3-1 provides details for the six evaluation criteria.

Table 3-1: Evaluation Criteria and Definitions

Criteria	Definition
Accuracy	The methodology comprehensively includes workload submission types in a manner that will likely forecast resource demands close to real world figures (e.g., submission volume).
Adaptable	The methodology can be scaled up as data and environment grow, expand, and change with new and evolving business needs.
Defensible	The objectives, inputs, mechanism, rationales, and expected outputs of the methodology are clearly defined. Methods and expected outputs are compatible with specified requirements.
Efficient	The methodology can be maintained in a manner that maximizes benefits, optimizes resources, and minimizes effort.
Feasible	The methodology can be implemented as planned and can be replicated and maintained in future years.
Meaningful	Expected methodology outputs are relevant and valid to the questions they are informing and are understood and accepted by decision-makers.

3.2 Data Collection and Analysis

To begin data collection and analysis per the established evaluation framework, Booz Allen conducted a baseline analysis of FDA's current artifacts that contribute towards the overall RCP. This required us to review the past and current methodology literature, proposed CPA methodology documentation, and relevant documentation for the GDUFA program related to financial practices, resource management, and the MTR framework. We validated our understanding through interviews and targeted discussions with FDA staff. We also used these sessions as platforms to solicit additional information not addressed in the documentation, as well as to gain additional insight regarding the historical context for initial model development.

Booz Allen aggregated all data and information collected into a central data repository. We then catalogued data according to the respective evaluation framework component, such as applicability of the CPA methodology and evaluation criteria. Afterward, Booz Allen conducted a detailed analysis, identified themes, and summarized findings and observations. Based on this analysis, we documented recommendations for the FDA should they decide to implement the proposed CPA methodology for the GDUFA program.

Figure 3-1 outlines the four key activities associated with the data collection and analysis process.

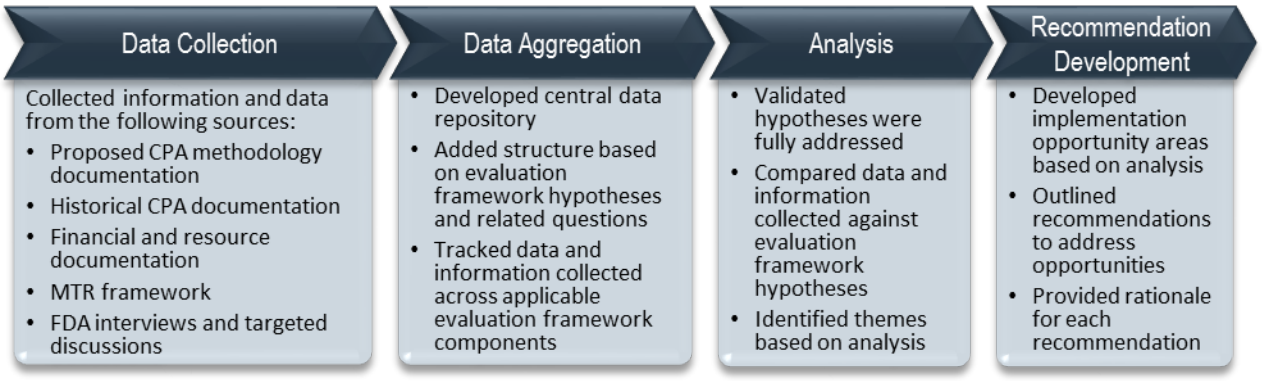

Figure 3-1: Data Collection and Analysis Approach

The following sections outline the outcome of these four key activities.

4 FINDINGS

Booz Allen analyzed data and information collected against the key hypothesis and evaluation criteria, as outlined in the evaluation framework. By doing so, Booz Allen collected evidence to evaluate whether FDA's proposed CPA methodology could be used to accurately assess changes in the resource needs and to monitor and report on those resource needs for the GDUFA program.

Overall, FDA's CPA methodology and current implementation state of RCP and MTR align conceptually to account for the sustained increases in GDUFA resource demand. Specifically, whether the GDUFA program could apply methodological framework and how the evidence compares to the evaluation criteria outlines the findings below as part of a structured assessment. The sections below outline Booz Allen's findings for the applicability of the CPA methodology and the evaluation criteria.

4.1 Overview of Findings

Based on Booz Allen's analysis, the proposed CPA methodology could be applied for the GDUFA program to accurately assess resource demand. The outputs generated from the overall CPA methodology could also meet the monitoring and reporting needs of the program. Booz Allen developed findings based on the proposed CPA's relationship to the definition of each evaluation criteria. These evaluation criteria and hypotheses align up to the overarching hypothesis that the proposed CPA methodology could be applied to the GDUFA program to accurately assess changes in the resource needs of the GDUFA program. The summary of evaluation findings in Table 4-1 describes the extent to which FDA's proposed CPA methodology addresses each of the evaluation criteria.

Table 4-1: Summary of Evaluation Findings

Evaluation Criteria	Findings
Accurate	The proposed CPA methodology for the GDUFA program would use a data-driven approach to predict the likely submission volume FDA will receive as part of the direct review workload. These predicted submission volumes would then be used to estimate resource needs for the GDUFA program with the use of time reporting data. As the proposed CPA methodology would capture major drivers of workload within the GDUFA program, FDA needs to explore all types of work that should be considered as direct review work and include them in the proposed CPA methodology to calculate accurate resource needs.
Adaptable	The proposed CPA methodology could adapt and account for a variety of data sources that may support the prediction of workload levels and resources needs of the GDUFA program. This methodology would utilize OSS with R and Python that gives the flexibility of incorporating various data formats. The managerial adjustment process would allow FDA to account for future business needs in the GDUFA program that may impact the CPA process. The methodology could act as a tool for the GDUFA program to use outside of fee setting for monitoring and reporting resource needs.
Defensible	The proposed CPA methodology would align to requirements set forth in the GDUFA II Commitment Letter. The overall CPA methodology and model development process are based on assumptions that FDA expects to remain true over time in the GDUFA program.
Efficient	FDA could use existing technology for forecasting and customize it to the unique challenges that are relevant in accurately estimating the upcoming workload level and resource needs of the GDUFA program. The use of the proposed CPA methodology for the GDUFA program could leverage a similar process used in the PDUFA and BsUFA programs that report resource needs to the industry stakeholders for promoting efficiency and consistency.
Feasible	Based on FDA's ability to build the initial set of workload forecast models and the availability of time reporting data that could be used to build the resource demand forecast models, there is evidence that FDA has the tools and data sources available to begin the implementation of the proposed CPA methodology in the GDUFA program. However, there are some offices outside CDER that currently support GDUFA activities but do not record time. These offices are expected to report their time in the future as a result of the MTR implementation.

Evaluation Criteria	Findings
Meaningful	FDA is developing and validating a managerial adjustment process within the proposed CPA methodology for the PDUFA and BsUFA programs. This approach will potentially look at factors of accuracy of previous years' forecasts, whether forecast resource needs are sustained over the next three years, hiring and attrition rate trends, and availability of other sources of funding. These factors could similarly be applied to the GDUFA program once finalized.

The section below provides additional details that provide context for each of the findings in Table 4-1, along with areas identified for enhancement as the proposed methodology and its inputs mature for each of the findings outlined above.

4.2 Evaluation Criteria Findings

4.2.1 ACCURATE

To evaluate accuracy, Booz Allen conducted an analysis to assess whether the model development process would likely represent the amount of submissions FDA receives for the GDUFA program. We also assessed whether all types of GDUFA program direct review workload would be captured in the RCP methodology to measure the amount of resources that are needed.

Accuracy of Workload Forecasts

The proposed CPA methodology would use a data-driven approach to predict the likely submission volume FDA will receive within the direct review workload types for the GDUFA program. Advanced analytical techniques through statistical analysis and machine learning would be used to build predictive models that forecast the submission volume for each of the direct review workload types. These predictive models would use internal and external data sources to identify leading indicators, which is information used to inform the forecast, and create a point estimate of the likely submission volume FDA will receive in the upcoming 3.5 fiscal years. To conduct a baseline check, FDA would also use another benchmark forecasting method, such as the three-year average, to compare the different outputs. Each of the point estimates from advanced analytical techniques and benchmark forecasting methods will be created using a specific date in the past. FDA would then evaluate the point estimates for accuracy using an error metric with the actual submission volume counts. More specifically, FDA would determine how close the estimated submission volume is to the actual submission volume. Depending on which approach gives the higher accuracy based on an error metric, FDA would use either the predictive model that uses advanced analytical techniques or the benchmark forecasting method to estimate the workload. FDA would perform this exercise for each of the direct review workload submission types.

This data-driven approach using advanced analytical techniques would allow FDA to be forward-looking and determine the amount of submissions that will be received in the GDUFA program. The predictive models would use leading indicators from internal and external data sources to help estimate the workload level FDA may have within the program. If the proposed CPA methodology does become a requirement and continues to be iterated yearly, it would require further evaluations to see the accuracy of the workload forecast models by comparing the actuals and predicted values of the submission counts. However, the proposed CPA methodology would have an iterative approach to continuously improve the workload forecast models. As more data becomes available, and once FDA can use the actual submission volume counts to evaluate the accuracy of the error metrics, FDA would continue enhancing the workload forecast models with additional data sources and advanced analytical techniques that may improve the accuracy of the workload forecast models.

Types of Direct Review Workload

The potential application of the CPA methodology to support the GDUFA program would capture major types of direct review workload to estimate the amount of workload FDA will receive in the upcoming fiscal years. FDA would then use this estimated workload to calculate the resource needs by analyzing historical level of effort required per application. Based on the resource needs estimates, FDA would then calculate additional resource needs that will be required within the current capacity of the GDUFA program. As the methodology continues to be developed and further mature, if implemented, FDA needs to explore all types of work that should be considered as direct review work and include them in the proposed CPA methodology to calculate accurate resource needs. This exploration would result in FDA analyzing the underlying data of the GDUFA program to see how it can build models to capture resource needs for these additional types of work. FDA has currently built initial workload forecast models for the direct review workload types outlined in Table 4-2.

Table 4-2: Direct Review Workload Types with Initial Workload Forecast Models[7]

Program	Direct Review Workload Types
GDUFA	ANDA Originals ANDA Original Resubmission / Amendments ANDA Supplements ANDA Supplement Resubmission / Amendments Controlled Correspondences

4.2.2 ADAPTABLE

Booz Allen evaluated whether the CPA methodology could scale to include further refined data in terms of new data sources, expanded data sources, and technological environment. We also assessed how the methodology could account for foreseeable future business needs, such as requirements, commitments, and priorities, and if the methodology could be used as a tool outside of fee setting for monitoring and reporting of GDUFA program resource needs.

Adaptability in Data and Technology

The proposed CPA methodology would be adaptable to account for a variety of data sources available that support the development of workload and resource demand forecast models for the GDUFA program. FDA would use advanced analytical techniques to analyze internal and external data sources to forecast submission volume. These advanced analytical techniques can support the inclusion of a variety of data sources. In addition, the proposed CPA methodology would utilize OSS with R and Python that have existing libraries to read data in a variety of formats that include structured, unstructured, and semi-structured data. If the proposed CPA methodology is adopted for the GDUFA program, the analysts could track potential additional data sources as well as changes in model development through the implementation process to reflect program specifics. The OSS with R and Python could also operate within different technological environments, such as cloud and on-premise technical infrastructures.

Foreseeable Business Needs

If the proposed CPA methodology is adopted for the GDUFA program, FDA would explore how to best structure the managerial adjustment process to make the most informed decisions for the GDUFA program. Part of this exploration could include examining what kind of additional information, such as future program requirements, commitments, and priorities, GDUFA stakeholders would require so that FDA could account for foreseeable business needs in the proposed CPA methodology. The Office of Generic Drugs (OGD) has identified examples of such needs like new statutory directives and changes in the complexity of drug submissions that could be explored. New statutory directives can occur during the year that would affect workload. To explore the increased complexity of generic drugs, GDUFA looks at human drug product information available from the PDUFA program about the type of submissions to expect in the future. Both are examples that allow the GDUFA program to identify future priorities before there is data to support it in the resource and workload forecasting models. As other stakeholders in the GDUFA program obtain experience on the potential CPA adoption, continued exploration of these needs would be tested. The managerial adjustment process would potentially look at factors of accuracy of previous years' forecasts, whether forecast resource needs are sustained over the next three years, hiring and attrition rate trends, and availability of other sources of funding. The managerial adjustment process has the potential to consider and adapt to qualitative factors such as future program requirements, commitments, and priorities.

Adaptable for Monitoring and Reporting

The purpose of the proposed CPA is to be a tool to predict resource needs for the GDUFA program and would be used to help fee setting, but it could also adapt to be a tool for monitoring and reporting of resource needs. Key industry stakeholders have expressed an interest in more transparency in FTE resource demand for the GDUFA program. One of the methodology outputs is resource demand count required in FTEs. FDA could integrate this into existing program reporting and perform the process annually. As a result, FDA could collect, explore, and monitor the data required for the methodological process continuously, and the proposed CPA methodology could serve as a multi-facet tool for the GDUFA program.

[7] Workload associated with drug master files (DMF) and certain industry meetings are captured in the initial workload forecast models developed by FDA as part of the ANDA Originals and ANDA Original Resubmission / Amendments. In addition, for ANDA Supplements and ANDA Supplement Resubmission / Amendments, the workload is captured across all supplements.

4.2.3 DEFENSIBLE

Booz Allen evaluated whether the defined objectives and methodology would align to requirements. We also assessed whether the methodology was based on assumptions that are reasonably expected to be/remain true in the GDUFA program.

Requirements

The proposed CPA methodology would align to requirements set in the GDUFA II Commitment Letter. A focus of the commitment letter is on enhanced accountability and reporting in the GDUFA program. In order to do this, a commitment was made to expand MTR and explore options associated with a methodology to assess changes in the resource needs for the GDUFA program and how to monitor and report on those needs. In 2018, FDA developed an implementation plan for MTR and GDUFA program resource management planning. CDER is currently implementing MTR for all offices associated with the PDUFA, BsUFA, and GDUFA programs direct review workload.

Booz Allen was tasked with performing this evaluation to see if the proposed CPA methodology would be useful for the GDUFA program to predict, monitor, and report on resource needs. The proposed CPA methodology consists of four components, each involving different inputs and producing different outputs. Each of the outputs could be used for monitoring and reporting on resource needs for the GDUFA program.

If the proposed CPA methodology is adopted by the GDUFA program, FDA would staff a cross-collaborative team comprised of workload and resource demand forecasting experts to meet the requirements set forth by the commitment letter to explore a methodology to assess changes in the resource needs. This cross-collaborative team will use best practices from data science which include: defining the business problem, developing hypotheses, gathering data, transforming data, analyzing data, engaging with the business subject matter experts (SMEs), modeling, validating the models, and documenting. These steps would be iterative in nature and the team would continue to explore how to make the proposed CPA methodology more robust.

Assumptions

High-level assumptions were identified during the evaluation of the proposed CPA methodology for the GDUFA program. These assumptions are based on the following themes: accuracy in time reporting data, the performance of the models, how the methodology will improve over time, and how the methodology will account for complexity. Booz Allen identified these assumptions in conjunction with FDA during the data collection and analysis process. Table 4-3 outlines these overall key assumptions and the rationale as to why they are reasonably expected to be and remain true for the GDUFA program.

Table 4-3: Assumptions

Assumption	Rationale
Time spent on direct review activities is accurately reported.	FDA employees receive time-reporting training and user guides to assist in the accurate reporting of time. In addition, FDA sends routine communication to FDA employees to raise awareness and keep them updated for any changes in time reporting. The two primary offices involved in the activities related to GDUFA program are OGD and Office of Pharmaceutical Quality (OPQ). These offices maintain a high level of time reporting compliance.
The model with the smallest error metric will provide the most accurate forecasts.	An error metric defines the potential performance and robustness of predictive models created using advanced analytical techniques. This error metric measures the potential accuracy in estimating the forecast to the actual values. The predictive model with the smallest error metric should best predict the workload level and resource needs.
The proposed CPA methodology will improve over time.	As the GDUFA program is in its second reauthorization, it is expected that it will continue to grow and expand. As it does, more data will be available for use. As the methodology evolves, FDA will expand and refine data, such as historical submissions volume and time reporting, which should improve the accuracy of the workload and resource demand forecast models. In addition, FDA will keep exploring advanced analytical techniques that may further improve the accuracy of these models.

Assumption	Rationale
Complexity changes in submission workload would be reflected in changes in time required per application.	Within the GDUFA program, the complexity of applications has increased over time. This complexity refers to a range of scientific and technical intricacies that are associated in the application review process. If the complexity on an average basis is increasing for any of the submission types of workload, the time reporting data would reflect that increase in average amount of time required per application.

Overall, these assumptions are sound and provide a baseline for future iterations of the proposed CPA methodology.

4.2.4 EFFICIENT

Booz Allen evaluated whether the methodology could be employed to support monitoring and reporting needs in a streamlined manner for the GDUFA program. In addition, we also evaluated whether the direct review submission types would have any unique challenges that would require complexities and customizations in the methodology to generate better outputs.

Monitoring and Reporting Needs

FDA is considering use of a similar conceptual framework of the proposed CPA methodology within the PDUFA and BsUFA programs that would adjust the target user fee revenue yearly to reflect any additional resource needs due to a sustained increase in workload. These adjustments would then be communicated to the industry stakeholders with the additional resource needs required for each program. FDA could leverage a similar process for the GDUFA program to report the additional resource needs to the industry stakeholders on a yearly basis. FDA would report the additional number of resources, in terms of FTE, and associated target revenue adjustments required to support the increase in workload in the GDUFA program in each fiscal year. This process would help ensure consistency and efficiency across the user fee programs.

Complexity and Customizations

FDA could use the existing technologies available for forecasting and customize it to the unique challenges that are relevant in accurately estimating the upcoming workload level and resource needs of the GDUFA program. The unique challenges in creating these estimations currently identified for the GDUFA program include the limited historical submissions data for some types of direct review workload. The overarching principle to use in the modeling efforts would be to reduce the error metrics of advanced analytical techniques and outperform the error metrics associated with the benchmark forecasting methods. FDA would choose these benchmark forecasting methods based on the availability and trends in the submission volume across each of the direct review workload types. FDA analysts involved in the model development process would achieve this objective by creating and testing multiple predictive models to meet the unique needs of estimating each of the direct review workload types. Based on the model performance results, FDA would choose a model with the smallest error metric for estimating the submission volume of each submission type. These predictive models would then go through a peer review process to ensure that each addressed the business question at hand and technical soundness of the models. FDA analysts would continue tracking a list of improvements and refinements for future model enhancements and will include these changes in the yearly iteration of the proposed CPA methodology if the accuracy in workload forecasts continues to improve.

4.2.5 FEASIBLE

Booz Allen evaluated whether tools and data sources employed by the methodology would be available. In addition, Booz Allen evaluated if the proposed CPA methodology development approach could be applied to the GDUFA program.

Tools and Data Sources

Based on FDA's ability to build the initial set of workload forecast models for the direct review workload types outlined in Table 4-2 and the availability of time reporting data that can be used to build the resource demand forecast models, FDA would have the tools and data sources available to begin the implementation of the proposed CPA methodology for the GDUFA program. However, there are some offices outside CDER that support the GDUFA activities but do not currently record time. Since MTR is undergoing rollout

based on the Resource Capacity Planning & Modernized Time Reporting Implementation Plan across the human medical product programs, these offices are expected to report their time in the future as a result of MTR implementation.[8]

Methodology Standardization

FDA has documented the overall conceptual framework of the proposed CPA methodology and outlines the steps to calculate the CPA factor for a user fee program. Currently, FDA is considering this framework for the PDUFA and BsUFA programs to adjust the annual target revenue based on the estimated workload level and any additional resource needs required by the program. A similar conceptual framework of the proposed CPA methodology would also work for the GDUFA program to help estimate the upcoming workload level and calculate any additional resource needs. FDA could build and expand upon the initial set of workload forecast models and create resource demand forecast models to accurately account for any additional resource needs in the GDUFA program. FDA could also further refine the managerial adjustment process and converting of adjusted FTE counts to actual cost that would be relevant for the GDUFA program.

4.2.6 MEANINGFUL

Booz Allen evaluated whether expected outputs would be interpretable and give relevant business insights (i.e., factors to make revenue adjustments) to decision-makers and whether the managerial adjustment of FTE would account for the necessary reasonableness factors to adjust the resource FTE count.

Interpretability and Utility

At the time of this assessment, FDA was developing the concept of managerial adjustment process within the proposed CPA methodology for the GDUFA program. This approach will potentially look at factors of accuracy of previous years' forecasts, whether forecast resource needs are sustained over the next three years, hiring and attrition rate trends, and availability of other sources of funding. The outputs of the models and additional information would align with what key factors decision-makers need when making decisions on FTEs requirements to meet workload demand for the GDUFA program. Table 4-4 outlines these factors and their rationales as to why they are reasonable to adjust the resource FTE count.

Table 4-4: Factors in Managerial Adjustment Process

Factors	Rationale
Accuracy of previous years' forecasts	The accuracy of the previous years' forecasts will help decision-makers understand how much to rely on the predictive models for calculating any additional resource needs.
Forecast resource needs are sustained over the next three years	By providing three years of forecast resource needs, the decision-makers would be able to assess if there will be a sustained workload to justify hiring of new FTEs.
Hiring and attrition rate trends	The hiring and attrition rate trends will help decision-makers understand the realistic number of net FTE gains that can happen for the following fiscal year.
Availability of other sources of funding	Availability of other sources of funding will help decision-makers understand if there are internal financial resources to support the additional FTEs needed.

The outputs of the models could provide stakeholders with transparency into the monitoring and reporting of the resource demands for the GDUFA program. The overall program amount for the GDUFA program would calculate the total number of FTEs and then convert that number into the total dollar amount. It would provide internal and external stakeholders a baseline of the total amount needed from the onset for FDA to sufficiently resourced to conduct review activities.

5 RECOMMENDATIONS

Booz Allen identified eight potential actions through evaluation of the data for FDA to consider if the GDUFA program decides to adopt the proposed CPA methodology. The intent of these recommendations is to support the FDA's intent to continuously improve the CPA as data, tools, and processes mature.

[8] Resource Capacity Planning & Modernized Time Reporting Implementation Plan. Retrieved from https://www.fda.gov/files/Resource-Capacity-Planning-and-Modernized-Time-Reporting-Implementation-Plan.pdf.

If FDA adopts, further develops, and iterates on the proposed CPA methodology for the GDUFA program, Booz Allen developed a set of recommendations that would provide FDA with opportunities to refine the CPA methodology's ability to forecast resource needs as the methodology matures and continuously improves over time. Table 5-1 provides a summary of these recommended actions for consideration should FDA adopt the methodology for the GDUFA program, along with the evaluation criteria impacted. FDA should evaluate if and when these recommendations should be incorporated into the CPA methodology over the course of a potential implementation.

Table 5-1: Summary of Recommendations

Recommendation	Relevant Evaluation Criteria
Related Direct-Review Work: FDA should perform data exploration that analyzes how to incorporate all types of review-related work into the workload and resource demand forecast models that are applicable for the proposed CPA methodology determined by the GDUFA program. FDA should continue exploring and capturing the resource needs for direct review workload types of ANDA Originals, ANDA Original Resubmission / Amendments, ANDA Supplements, ANDA Supplement Resubmission / Amendments, and Controlled Correspondences. FDA could further consider capturing resource needs for the workload associated with 1) post-approval and pre-ANDA submission work that include submission types related to post-market safety and surveillance, policy and guidance development, the GDUFA II Pre-ANDA program, PFC, requests for CPAM, method validation program, and dispute resolutions; and 2) submissions that have an internal review performance goal but no performance metric goal within the GDUFA II Commitment Letter and, subsequently, no required timeline for review. FDA may want to implement the models at the appropriate level of detail for each of the direct review workload types, prior to breaking out these models into distinct characteristics of each submission type.	Accurate Feasible Meaningful
Modernized Time Reporting Formal Implementation Plan: FDA should create a formal implementation plan for adding the capabilities of MTR in each of the remaining offices that perform direct review workload activities within the GDUFA program but currently do not have a formal plan yet created.	Accurate Defensible
Managerial Adjustment Process Development: FDA could refine the managerial adjustment process for the GDUFA program with additional steps and data to help make informed decisions by: 1) evaluating the accuracy of adjustments made in the previous fiscal years' managerial adjustment process, 2) exploring the development of business scenarios to be included in the managerial adjustment process in future years, and 3) generating hiring metrics that outline how long it takes on average to hire new FTEs by job role and discipline.	Adaptable Meaningful
Reporting of Resource Needs: FDA should follow a similar process used by the PDUFA and BsUFA programs for the GDUFA program to monitor and report the resource needs by utilizing 1) the Generic Drug User Fee Rates Federal Register Notice, 2) the annual financial reports, and 3) the five-year financial plans.	Adaptable Efficient Meaningful
Evaluation of Time Reporting Data Collection Process: Once FDA finalizes the types of direct review workload that will be included in the proposed CPA methodology for the GDUFA program, FDA should evaluate the structure of the time reporting categories associated with each of the direct review workload types to ensure it is optimally designed to accurately predict resource needs.	Accurate Feasible
Prediction Intervals: FDA may consider whether creating prediction intervals for the resource demand forecasts would add practical value for the decision-makers in the managerial adjustment process to assess the future uncertainty in the mean estimates and make relative adjustments.	Accurate Meaningful
Model Interpretability: FDA may consider whether increasing interpretability within the complex models used in advanced analytical techniques for workload forecasting would help inform the managerial adjustment process by providing insights as to why the models are estimating specific number of submissions.	Accurate Meaningful
Methodology Documentation: If the proposed CPA methodology does become a requirement as part of the GDUFA program target revenue fee adjustments, FDA should consider developing the overall methodology assumptions, rationales, and procedures in the technical appendices and related documentation to provide a baseline as the methodology evolves over time.	Adaptable Defensible Efficient

The following sections provide additional details to the recommended actions summarized in the table above.

5.1 Related Direct-Review Work

FDA should perform data exploration that analyzes how to incorporate all types of review-related work into the workload and resource demand forecast models that are applicable for the proposed CPA methodology determined by the GDUFA program. Along with continuing to explore and capture resource needs for the direct review workload types outlined in Table 4-2, below are few suggestions that may help FDA capture additional resource needs with further accuracy for the GDUFA program:

- FDA could consider including workload associated with post-approval and pre-ANDA submission work that include submission types related to post-market safety and surveillance, policy and guidance development, the GDUFA II Pre-ANDA program, PFC, requests for CPAM, method validation program, and dispute resolutions as part of the direct review work.

- FDA could consider including workload associated with submissions that have an internal review performance goal but no performance metric goal within the GDUFA II Commitment Letter and, subsequently, no required timeline for review. To capture the resource needs for these submission types, FDA should start with analyzing the time reporting data associated with the actual number of applications reviewed and capture the level of effort per application. FDA would then work with the business stakeholders to understand the internal review performance goal they would like to meet for the upcoming fiscal years. FDA would use the metrics from these steps to appropriately calculate the resource needs associated with the review of these applications.

If the proposed CPA methodology is adopted within the GDUFA program, FDA would account for the resource needs across all the major drivers of workload. FDA may want to explore creating the workload and resource demand forecast models with the above suggestions. This data exploration would help FDA identify how to incorporate all potential review-related workload types into the proposed CPA methodology and calculate any resource needs with further accuracy for the GDUFA program.

FDA may also want to implement the models at the appropriate level of detail for each of the direct review workload types in the beginning, if the proposed CPA methodology is adopted for the GDUFA program. FDA could make sure the methodology is properly accounting for resource needs before establishing any complex modeling approach associated with the distinct characteristics of each submission type.

5.2 Modernized Time Reporting Formal Implementation Plan

FDA should create a formal implementation plan for adding the capabilities of MTR in each of the remaining offices that currently do not have a formal plan yet created but perform direct review workload activities within the GDUFA program. MTR refers to the enhancements within FDA's activity-based time utilization data collection process to allow staff engaged in the user fee programs for reporting how they spend their time on certain activities. FDA has planned that all the offices who support the GDUFA program would have the MTR capabilities by the end of fiscal year 2022. Although most offices have or are executing MTR plans, a formal implementation plan for each of the remaining offices would help this process for FDA by outlining the tasks, resources, and timeline needed to add the MTR capabilities in each of the offices. With the MTR capabilities added, FDA would then have the proper time reporting data in all the remaining offices if the CPA methodology does become a requirement for the GDUFA program. Each office's workload level and resource needs would then be properly accounted for to ensure they have the proper support to meet the performance goals listed in the commitment letter.

5.3 Managerial Adjustment Process Development

FDA could continue developing and refining the managerial adjustment process for the GDUFA program. Listed below are a few suggestions that may help FDA make further informed decisions.

- FDA should consider evaluating the accuracy of adjustments made in the previous fiscal years' managerial adjustment process. FDA can document the underlying assumptions and rationale used in this process and analyze how these assumptions performed. If previous adjustments were too high or too low, FDA can evaluate the decisions made and identify the changes needed in the decision-making framework for continuous improvements.

- FDA is exploring the development of business scenarios to include in the managerial adjustment process for future years. This information will help the decision-makers understand the dynamics associated with changes in program requirements, such as statutory directives, commitments, and priorities. FDA should collaborate with relevant stakeholders to identify and

document these business scenarios. In addition, FDA should implement and validate rigorous decision frameworks for how to identify these business scenarios and support objectivity and consistency.

- FDA should consider generating hiring metrics that outline how long it takes on average to hire new FTEs by job role and discipline. These metrics will help the decision-makers understand the feasibility and timing of onboarding the new FTEs identified to ensure FDA meets the resource needs of the user fee programs. This recommendation is contingent on the ability of FDA human resources systems to provide these insights.

5.4 Reporting of Resource Needs

FDA should use the existing reporting mechanisms to monitor and report on resource needs to industry stakeholders per the requirements stated in the GDUFA II Commitment Letter. For efficiency, FDA may follow a similar process as the PDUFA and BsUFA programs to monitor and report on such needs. To fulfill the commitment letter requirement, FDA could report on FTE resource demand and FTE counts in the annual financial reports and the five-year financial plans. Currently, there is a section in the annual financial report on FTEs that reports out FTE by year and center. To mirror other user fee programs, the section should expand to include information on planned hiring by organization showing target verses actual hiring and the reasons for the discrepancies. In the five-year plan, the GDUFA program could report on the growth in the various submission types and expand on planned hiring. Expanding these sections of the reports would provide greater transparency of the existing and future resources with the industry stakeholders. If a CPA is required in the future, the GDUFA program should consider outlining the fee revenue adjustment for capacity planning in the Generic Drug User Fee Rates Federal Register Notice. It could mirror how the PDUFA program currently reflects its CPA adjustments in the Prescription Drug User Fee Rates Federal Register Notice.

5.5 Evaluation of Time Reporting Data Collection Process

Once FDA finalizes the types of direct review workload that will be included in the proposed CPA methodology for the GDUFA program, FDA should evaluate the time reporting categories structure associated with each of the direct review workload types to ensure it is optimally designed to accurately predict resource needs. FDA would need to understand the tradeoffs between the utility of data related to the amount of time spent in conducting activities and complying with the requirement of reporting hours at appropriate levels of detail for the GDUFA program. If FDA should choose to collect time reporting data at an application level, FDA could potentially identify additional submission-related factors that require higher resource needs. Determining the appropriate level of time reporting category structure could help FDA further account for complexity for each of the direct review workload types. This complexity refers to a range of scientific and technical intricacies that are associated in the application review process. These factors may help FDA calculate any additional resource needs with further accuracy for the GDUFA program.

5.6 Prediction Intervals

FDA may consider whether creating prediction intervals for the resource demand forecasts would add practical value for the decision-makers in the managerial adjustment process. A prediction interval is a range with an upper and lower limit between which the expected resource needs lie, based on a certain probability. Using these prediction intervals, the decision-makers could assess the future uncertainty in the mean estimates produced by the resource demand forecast and make relative adjustments. If there is a high level of future uncertainty based on the prediction intervals, the managerial adjustment process may want to be conservative in the adjustments on the mean estimates of resource demand forecasts. This information would help supplement the other factors to consider in the managerial adjustment process. FDA would need to implement and validate a rigorous decision framework to ensure objectivity and consistency. The prediction intervals may lead to additional accuracy in adjustments to resource demand forecasts by providing more insights into their uncertainty. This may also help provide additional meaningful outputs for the decision-makers involved in the managerial adjustment process.

5.7 Model Interpretability

FDA may consider whether increasing interpretability within the complex models used in advanced analytical techniques for workload forecasting would help inform the managerial adjustment process. Model interpretability is an exercise that can help FDA further understand why the models are estimating specific number of submissions. This exercise also helps provide insights into how different values in variables from data sources play a role on the forecasts. Using this analysis, FDA may have an increased trust within the advanced analytical techniques that generate the submission volume forecasts to help with the accuracy and allow more transparency when communicating the forecasts to the decision-makers. FDA may also use the outputs of model interpretability exercise to

understand the impact on workload and resource needs from various "what-if" business scenarios. Additionally, FDA could develop these business scenarios for the decision-makers, in collaboration with stakeholders, to produce only relevant qualitative factors. The model interpretability and the application of "what-if" business scenarios may help provide additional meaningful outputs to the decision-makers involved in the managerial adjustment process. These enhancements may also increase the accuracy of the adjustments to the resource demand forecasts.

5.8 Methodology Documentation

FDA should consider enhancing the documentation of the proposed CPA methodology to include:

- The overall methodology assumptions of the CPA methodology for the GDUFA program. As the methodology matures, FDA should revise and enhance the assumptions for the overall process to reflect various iterations of the methodology. If the assumptions prove to be incorrect, this documentation will provide a baseline for the needed revisions to enable adaptability of the methodology over time.
- Historical documentation of the rationale of decision-making in the model development process to support FDA with future analysis that enhances efficiency by providing a baseline for the needed revisions. Since FDA would iterate the proposed CPA methodology yearly, understanding the reasons behind the process would help to interpret the unique aspects of models built for each of the direct review workload types. By documenting the rationale behind decisions made, future iterations of the model development could utilize this information for continuous improvements. Rationale would also support the justification of each model's creation to support a transparent process and help with knowledge transfer.
- A set of standard operating procedures to promote replicability and transparency over time. This will allow the FDA to perform the methodology each year in a standard format regardless of the FDA staff involved.

This documentation would support a more defensible overall CPA methodology with clearly defined assumptions, rationales, and procedures. In addition, the documentation would provide transparency and enhanced communication with stakeholders.

6 APPENDIX

This section includes additional information and analyses to support the evaluation findings and recommendations.

6.1 Appendix A: Glossary

Table 6-1 includes a glossary of terms used in this assessment.

Table 6-1: Glossary of Terms

Abbreviation	Definition
ANDA	Abbreviated New Drug Application
BsUFA	Biosimilar User Fee Amendments
CDER	Center for Drug Evaluation and Research
CPA	Capacity Planning Adjustment
CPAM	Combination Product Agreement Meetings
DMF	Drug Master Files
FDA	Food and Drug Administration
FDARA	FDA Reauthorization Act of 2017
FD&C Act	Federal Food, Drug, and Cosmetic Act
FTE	Full-Time Equivalent
GDUFA	Generic Drug User Fee Amendments
MTR	Modernized Time Reporting
OGD	Office of Generic Drugs
OPQ	Office of Pharmaceutical Quality
OSS	Open-Source Software
PDUFA	Prescription Drug User Fee Act
PFC	Pre-Submission Facility Correspondence
RCP	Resource Capacity Planning
SME	Subject Matter Expert
TAG	Technical Advisory Group

6.3 Appendix B: Documentation of Sources

Table 6-2 includes a list of references used in this report.

Table 6-2: References

No.	Document Name	Date Created/Last Modified
1	FDA Reauthorization Act of 2017	8/18/2017
2	Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 – Guidance for Industry	10/2019
3	GDUFA II Commitment Letter	8/1/2018
4	Resource Capacity Planning and Modernization Time Reporting Implementation Plan	3/2018
5	FY 2018 GDUFA Financial Report required by the Generic Drug User Fee Amendments	10/2018
6	GDUFA FY 2019 Fee Amount	10/31/2019
7	User Fee Financial Reports	3/28/2018
8	User Fee Performance Reports	3/29/2018
9	User Fee Five-Year Financial Plans	5/31/2019
10	Authorization of Generic Drug Program	7/9/2012
11	Generic Drug User Fee Rates for Fiscal Year 2020	7/26/2019