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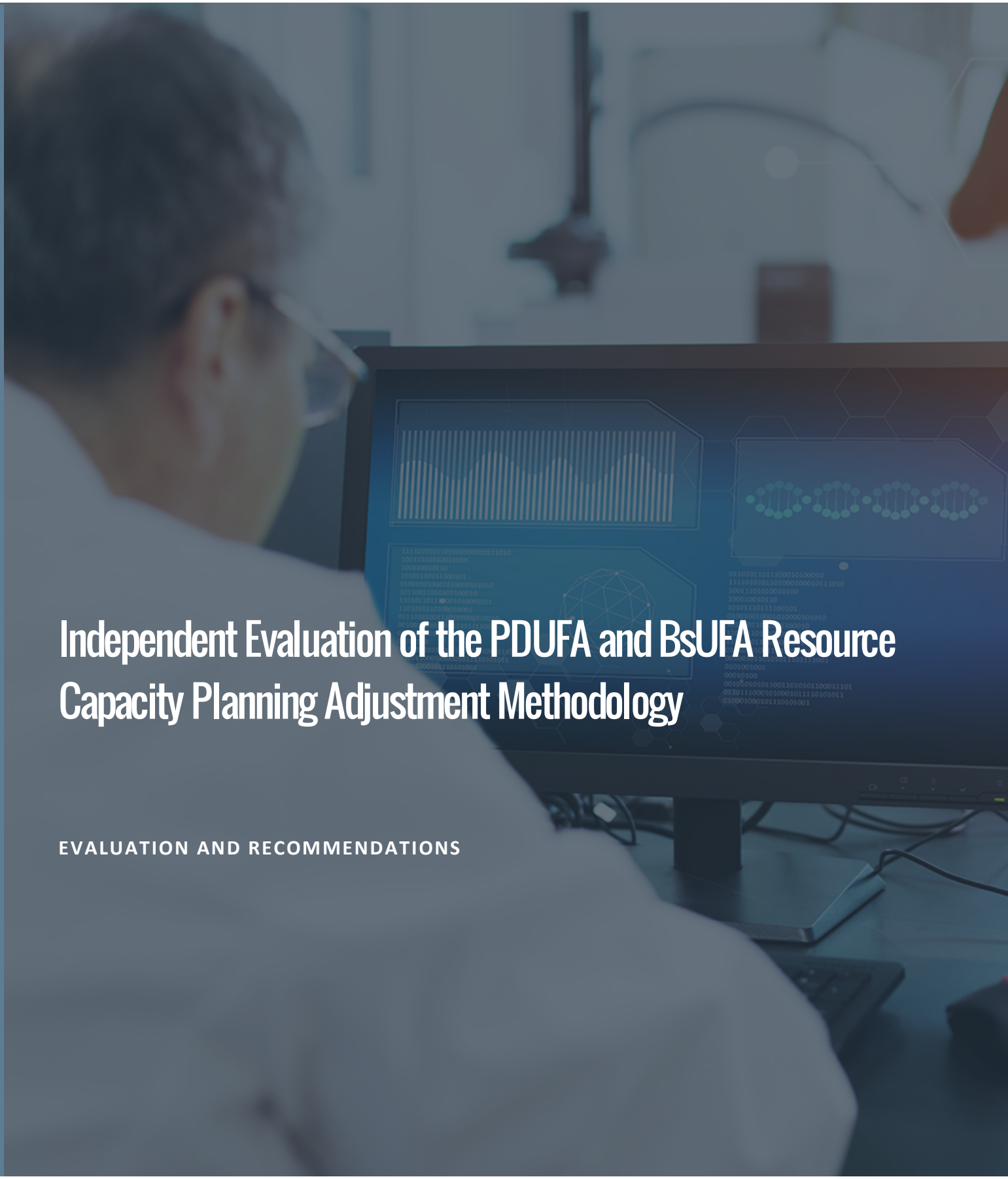

Independent Evaluation of the PDUFA and BsUFA Resource Capacity Planning Adjustment Methodology

EVALUATION AND RECOMMENDATIONS

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EXECUTIVE SUMMARY

Booz Allen evaluated the Food and Drug Administration's (FDA) proposed capacity planning adjustment methodology to calculate the annual fees for human drugs and biosimilar biologics under the FDA Reauthorization Act of 2017. The report examines the options and recommendations for the proposed capacity adjustment methodology to accurately assess changes in the resource and capacity needs for prescription drug and biologic biosimilar user fee direct review work.

The FDA Reauthorization Act of 2017 (FDARA) includes provisions for the independent assessment of the Food and Drug Administration's (FDA) Capacity Planning Adjustment (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 and the current state of maturity. This report evaluates the options and recommendations for the CPA to accurately assess changes in the resource and capacity needs of the human drugs and biosimilar biological product review programs[2] based on the proposed use of the initial core set of forecasting models.

As part of the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Amendments (BsUFA) II commitments, FDA is developing a Resource Capacity Planning (RCP) function and implementing a modernized time reporting approach to enhance the management of user fee resources. The proposed CPA methodology will adjust the annual base revenue to reflect changes in the resource capacity needs to review human drug, biologic, and biosimilar product submissions. At a high level, the process includes first calculating the workload forecast to estimate the volume by type of submission. Second, FDA will 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 will apply a managerial adjustment to ensure the CPA adjusts only for new resources that cannot be supported through existing funds.[3] Using the final FTE value from the managerial adjustment, FDA will subsequently convert FTEs to dollars. FDA will then add the resulting value to the annual target revenues for PDUFA and BsUFA 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 feedback to validate program-wide objectives and methodology design considerations. After evaluating all data collected through the hypothesis-driven framework, Booz Allen developed findings based on the proposed CPA's relationship to the definition of each evaluation criteria. Evaluation criteria and hypotheses align up to an overarching hypothesis that the proposed CPA methodology is an improvement from previous practices. Overall, FDA's proposed CPA methodology aligns with the objective to develop a methodology to account for the sustained increases in PDUFA and BsUFA resource needs to perform reviews. In addition, the proposed CPA methodology includes improvements that address key issues from previous workload and resource adjustment methods. The summary of evaluation findings describes the extent to which FDA's proposed methodology addresses 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 with the maturation of the proposed CPA. 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] Human drug and biosimilar biologic program activities include work outside of submission reviews. The resource and capacity needs of the proposed CPA forecasts align with direct review submission activities. A list of submission types is in Table 2-3: Direct Review Submission Categories for Respective User Fee.

[3] For this report, resource needs are defined as personnel and related support costs.

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), and results will likely be reliable and unbiased.	The workload forecast models will likely represent the amount of submissions FDA receives based on the approach used to predict submission volume. The proposed CPA methodology captures major types of direct review workload to measure the amount of resources needed within the current capacity when there are sustained increases in the workload. As the maturity of the proposed CPA methodology grows, further evaluations will be required to see the accuracy of the workload forecast models by comparing the actuals and predicted values of the submission counts.
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 is adaptable to account for new and expanded data sources. This methodology utilizes open-source software (OSS) with R and Python that gives the flexibility of reading a variety of data formats. These OSS with R and Python can also operate within different technological environments. The managerial adjustment process can help FDA account for foreseeable future business needs that may impact the CPA process.
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 aligns to requirements set in FDARA and the PDUFA VI and BsUFA II commitment letters. FDA has developed a consensus around this methodology through a series of working groups who have domain expertise regarding the workload and resource needs for PDUFA and BsUFA. The overall CPA methodology and model development process are based on assumptions that FDA expects to remain true over time.
Efficient	The methodology can be maintained in a manner that maximizes benefits, optimizes resources, and minimizes effort.	FDA plans to create a technical infrastructure that can support components related to automation and operationalization of the model development process. FDA uses existing technology for forecasting and customizes to the unique challenges that are relevant in estimating the workload level and resource needs. By customizing the use of advanced analytical techniques to help produce accurate forecasts, FDA addresses these unique challenges.
Feasible	The methodology can be implemented as planned and can be replicated and maintained in future years.	The overall paradigm of the proposed CPA methodology is documented fully and outlines the steps used to calculate the CPA factor for PDUFA and BsUFA. Based on FDA's ability to build the initial core set of workload and resource demand forecasting models that use actual data, there is evidence that FDA has the tools and data sources available to begin the implementation of the proposed CPA methodology.
Meaningful	Expected methodology outputs are relevant and valid to the questions they are informing and are understood and accepted by decision-makers.	The managerial adjustment process within the proposed CPA methodology 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 potential decision factors were verified to be interpretable by the decision-makers and will likely give them relevant business insights to help make informed decisions.

Overall, FDA's CPA methodology and current implementation state of RCP and modernized time reporting align conceptually with the objective to develop a methodology to account for the sustained increases in PDUFA and BsUFA user fee program workload. The initial core set of forecasting models, modernized time reporting practices, and data harmonization efforts should enable FDA to assess the resource needs of the program, which it will be able to validate once FDA has sufficient time reporting data and data to compare the number of submissions and effort to those forecasted by the models. Booz Allen's recommendations provide FDA with opportunities to refine understanding of how current and future data influence the resource forecast models as they mature and continuously improve over time. Table 2 provides a high-level description and alignment of recommendations to the evaluation criteria.

Table 2: Summary of Recommendations

Recommendation	Relevant Evaluation Criteria
Prediction Interval: 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
Related Direct Review Workload: FDA may want to perform data exploration that analyzes how other, more complex types of direct review work, such as post-market safety and some subsets of policy and guidance development, could be incorporated into the methodology, which will enhance the accuracy in resource demand forecasts.	Accurate Adaptable
Managerial Adjustment Process: FDA may continue refining the managerial adjustment process 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.	Accurate Meaningful
Methodology Documentation: FDA should consider including the overall methodology assumptions, rationale, and procedures in related documentation to help provide a baseline as the methodology evolves over time.	Adaptable Defensible Efficient

1 INTRODUCTION

FDARA requires FDA to develop a new CPA methodology that accounts for sustained increases in workload for the human drug and biosimilar biologics program. FDA contracted Booz Allen to conduct an assessment focused on evaluating the FDA's proposed resource capacity planning adjustment methodology for determining the resource needs of the PDUFA and BsUFA programs. This section provides an overview of the project background and objectives of this 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.[4] 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.

To make the human drug and biosimilar biologic product review process more efficient, while maintaining product safety, efficacy, and quality, Congress enacted PDUFA in 1992 and BsUFA in 2012. Developed in cooperation with the biopharmaceutical industry ("industry"), each authorizes FDA to charge a fee to supplement non-user fee appropriations from Congress for the review of certain human drug, biologic, and biosimilar biological product submissions. Specifically, the additional funding from user fees provides FDA with the resources to meet established and agreed-upon performance goals for the direct review activities of specific PDUFA and BsUFA submissions. Through consultation with scientific and academics experts, health care professionals, and representatives of

[4] The Prescription Drug User Fee Act (PDUFA). Retrieved from https://www.govinfo.gov/content/pkg/STATUTE-106/pdf/STATUTE-106-Pg4491.pdf#page=8.

patient and consumer advocacy groups, FDA negotiates the performance and financial commitments that establish requirements for user fee revenue amounts and a new set of measurable goals for the programs.

For human drugs, PDUFA sets the total revenue base amount for the fiscal year (FY) and then FDA adjusts for inflation and other program-specific needs, such as operating reserve and additional direct costs, to determine the target revenue amount for the fiscal year. FDA then divides the target revenue amount by estimates of PDUFA applications to set the fee amounts. For biosimilar biologics, BsUFA similarly sets the total revenue base amount and then FDA adjusts for inflation and workload costs to determine the target revenue amount for the fiscal year. FDA then divides the target revenue amount by estimates of BsUFA applications to set the fee amounts. For both programs, FDA publishes these amounts in the Federal Register prior to each new fiscal year. With each reauthorization, the scope of the program expands to account for new policies, product innovations, and other program needs.

Over time, the technical complexity of scientific reviews and volume of application submissions increased, and FDA identified that additional funding was critical to meet performance goals and advance the program. For example, PDUFA V commits user fee funds to establish a program to increase efficiency through greater transparency and communication with industry for new molecular entity new drug applications (NME NDA) and original biologics license applications (BLA).[5] In 2003, PDUFA III introduced the PDUFA Workload Adjuster ("workload adjuster"), with the objective to ensure the revenue is available to fund increasing workload. With the new workload adjuster, FDA implemented a four-step methodology for each submission type in the adjuster:

1) Calculate the current five-year rolling average number of new submissions and base five-year submissions
2) Calculate the percent change in five-year rolling average number of new submissions
3) Multiply the percent change in volume by a weighting factor reflective of the proportion of total direct review work of each submission type
4) Add the weighted percentage change in volume for each submission type to calculate the total percentage change as the adjustment factor

FDA continued to evolve and address issues with the workload adjuster in PDUFA IV and V by changing the measurement of investigational new drug (IND) applications and introducing a complexity factor to account for changes in average workload per submission. Through a public process of research and evaluation, FDA made additional changes to the workload adjuster: 1) shifting from a five-year rolling average to a three-year rolling average, and 2) discontinuing the complexity factor.[6]

FDARA describes the fee-setting process for PDUFA, which includes the interim CPA methodology.[7] In addition, FDARA includes a process for adopting a new CPA methodology for PDUFA and BsUFA that accounts for sustained increases in submission workload for the human drug and biosimilar biological programs. To advance the approach to calculate the target revenue beyond the interim CPA methodology, FDA's proposed CPA methodology integrates the activity-based time reporting data from FDA's concurrent Modernized Time Reporting (MTR) initiative to capture year-round reporting. FDARA and the commitment letters call for an independent evaluation of FDA's proposed CPA methodology.

1.2 Objectives

The key objectives of this evaluation include:

- Evaluate FDA's proposed CPA methodology to assess the sustained workload and resource needs of the PDUFA and BsUFA user fee programs in comparison to the interim CPA methodology
- Provide recommendations and considerations that could feasibly improve the proposed CPA methodology

[5] PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017. Retrieved from https://www.fda.gov/media/81306/download.

[6] PDUFA IV allowed the expansion of the workload adjuster to include an adjustment for changes in review activities for NDAs/BLAs and active commercial INDs, which is known as the "complexity factor."

[7] Prescription Drug User Fee Rates for Fiscal Year 2020. Retrieved from https://www.federalregister.gov/documents/2019/08/02/2019-16435/prescription-drug-user-fee-rates-for-fiscal-year-2020.

2 FDA CAPACITY PLANNING ADJUSTMENT METHODOLOGY OVERVIEW

The intent of the proposed CPA methodology is to adjust the annual target revenue to account for sustained increase in workload for the human drug and biosimilar biologics programs. Currently, an interim CPA methodology exists for PDUFA that uses a four-step calculation-based process to determine the capacity planning adjustment factor. FDA is proposing a CPA methodology that will use a four-step structured and data-driven process to determine the adjustment factor for both PDUFA and BsUFA.

2.1 Introduction to Capacity Planning Adjustment

The target revenue methodology is an annual process defined in statute that outlines all the adjustments made to each year's base revenue to calculate the target revenue for the following fiscal year. The CPA is one of the adjustments applied during this process. The purpose of the CPA is to modify the base revenue for PDUFA and BsUFA to reflect the changes in resource needs for application and license reviews. CPA occurs once FDA applies the inflation adjustment and prior to any other program-specific adjustments for the upcoming fiscal year. Figure 2-1 and Figure 2-2 illustrate the PDUFA and BsUFA annual target revenue methodologies, respectively, to provide context as to how the interim and proposed CPA is integrated into the overall process.

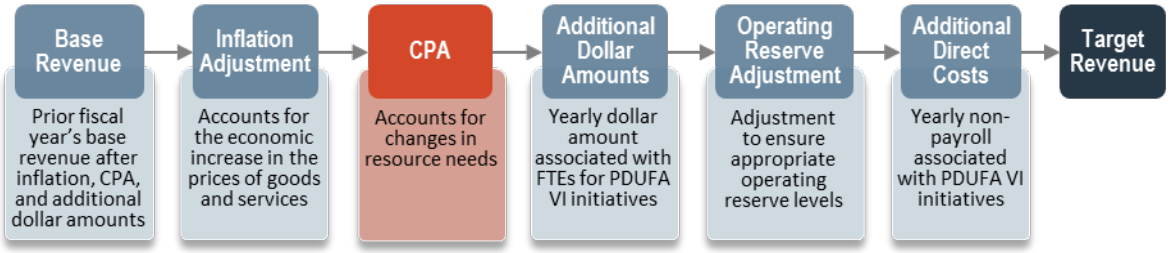

Figure 2-1: PDUFA Target Revenue Methodology

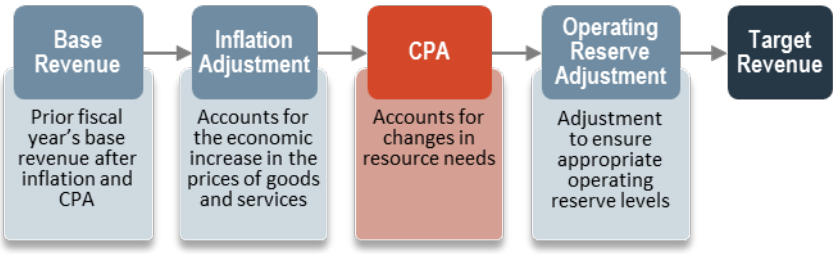

Figure 2-2: BsUFA Target Revenue Methodology

The interim CPA methodology was implemented as a short-term solution, per the 736(c)(2)(B) of Food, Drug & Cosmetic (FD&C) Act, for the known issues with the previous PDUFA V Workload Adjuster, while allowing for more time to propose a new and more robust CPA methodology.[8] Overviews of the interim and proposed CPA methodologies are provided in Section 2.2 and Section 2.3, respectively. These sections discuss the key steps used to calculate the CPA factor that FDA applies to the annual target revenue. Table 2-1 provides a description of key concepts that are important for understanding both CPA methodologies.

[8] PDUFA V Workload Adjuster Evaluation Final Report. Retrieved from https://www.fda.gov/media/93701/download.

Table 2-1: Key CPA Concepts

Concept	Description
Direct Review Work	Work directly related to the review of types of submissions under PDUFA and BsUFA that is considered in-scope for the CPA methodology
Indirect Review Work	Work that supports review and other regulatory work related to PDUFA and BsUFA, but not within scope of direct review work and the CPA methodology
Internal Support Work	Work related to an employee's lifecycle 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 will receive
Resource Demand	Number of FTEs required to support the workload, including both direct review and internal support
Capacity	Estimated available allocated hours among all the existing resources for the user fee 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

2.2 Interim Capacity Planning Adjustment Methodology

Currently, only PDUFA employs the interim CPA methodology, which uses a four-step calculation-based process to determine the adjustment factor as outlined in Figure 2-3.

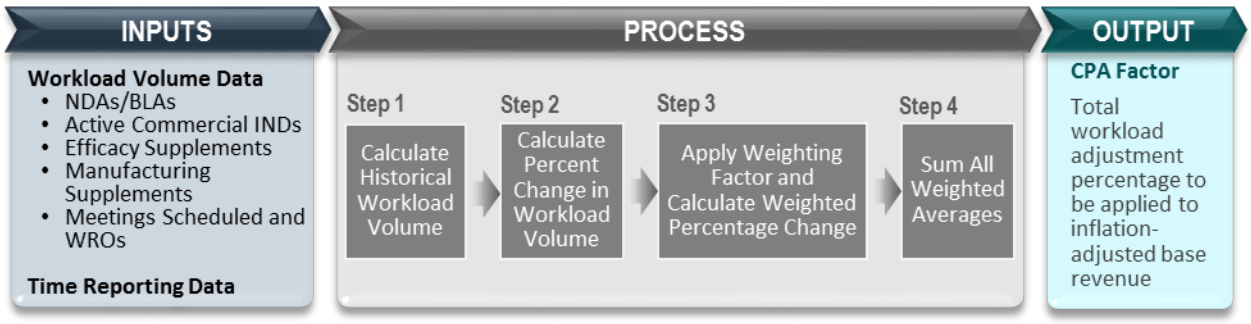

Figure 2-3: Interim CPA Methodology Overview

Each step below describes the process used within the interim CPA methodology at a high level.

Step 1: Calculate Historical Workload Volume

The first step of the interim CPA process is to calculate the historical workload volume. FDA captures the historical workload volume by gathering the historical submission volume data for the following five direct review workload submission categories:

- NDAs/BLAs
- Active Commercial INDs
- Efficacy Supplements
- Manufacturing Supplements
- Formal Meetings Scheduled: Type A, B, B (End of Phase), C, and Written Response Only (WRO)

Once FDA captures the historical submission volume data, FDA calculates a three-year average volume as of the previous and current fiscal year for each of the five direct review workload submission categories.

Step 2: Calculate Percent Change in Workload Volume

The second step of the interim CPA process is to calculate the percentage change in workload volume. Using the three-year averages calculated in Step 1, FDA calculates a percentage change between the three-year averages across the two fiscal years for each of five direct review workload submission categories. This percentage change helps capture the trends in changes to workload.

Step 3: Apply Weighting Factor and Calculate the Weighted Percentage Change

The third step of the interim CPA process is to apply a weighting factor and calculate the weighted percentage change. FDA calculates the weighting factor for each of direct review workload submission categories using the time invested in activities related to the specific direct review workload submission category as a percentage of total time invested in all PDUFA activities. The weighting factor helps capture the relative level of effort for each of the five direct review workload submission categories. Using the weighting factors, FDA then multiplies each weighting factor with the respective percentage change calculated in Step 2 to get the weighted percentage change for each of direct review workload submission categories.

Step 4: Sum All Weighted Averages

The fourth step of the interim CPA process is to sum all the weighted percentage changes calculated in Step 3 across the five direct review workload submission categories to get the total CPA percentage. FDA applies the total CPA percentage as the adjustment factor to the inflation-adjusted annual base revenue to reflect the changes in resource capacity needs for the process of human drug application reviews in PDUFA.

Table 2-2 provides an example of how these steps operate within the interim CPA methodology. Specifically, it outlines how FDA calculated the capacity planning adjustment factor for PDUFA in fiscal year (FY) 2020, per the Prescription Drug User Fee Rates for FY 2020 Federal Register notice.[9]

Table 2-2: Interim CPA Methodology Calculation for PDUFA in FY 2020

Submission Category	Step 1		Step 2	Step 3	
	3-Year Average Ending FY 2018	3-Year Average Ending FY 2019	Percentage Change	Weighting Factor	Weighted Percentage Change
NDA/BLAs	162.00	168.67	4.1152%	16.5464%	0.6809%
Active Commercial INDs	8057.00	8335.67	3.4587%	22.2644%	0.7701%
Efficacy Supplements	234.33	262.33	11.9488%	4.1340%	0.4940%
Manufacturing Supplements	2561.67	2578.67	0.6636%	5.2980%	0.0352%
Meetings Scheduled and WROs	3136.33	3295.33	5.0696%	5.7119%	0.2896%
FY 2020 Capacity Planning Adjuster					**Step 4** 2.2697%

The capacity planning adjustment of 2.2697% is then multiplied to the inflation-adjusted annual base revenue of $1,025,479,049 that results in the capacity planning adjustment cost of $23,275,298. This cost is then added to inflation-adjusted annual base revenue of $1,025,479,049, resulting in the inflation and capacity planning adjusted amount of $1,048,754,347 for PDUFA in FY 2020.

2.3 Proposed Capacity Planning Adjustment Methodology

FDA is proposing to use a new robust CPA methodology for both PDUFA and BsUFA that uses a four-step structured and data-driven process to determine the adjustment factor as outlined in Figure 2-4 for PDUFA and Figure 2-5 for BsUFA.

[9] Prescription Drug User Fee Rates for Fiscal Year 2020. Retrieved from https://www.federalregister.gov/documents/2019/08/02/2019-16435/prescription-drug-user-fee-rates-for-fiscal-year-2020.

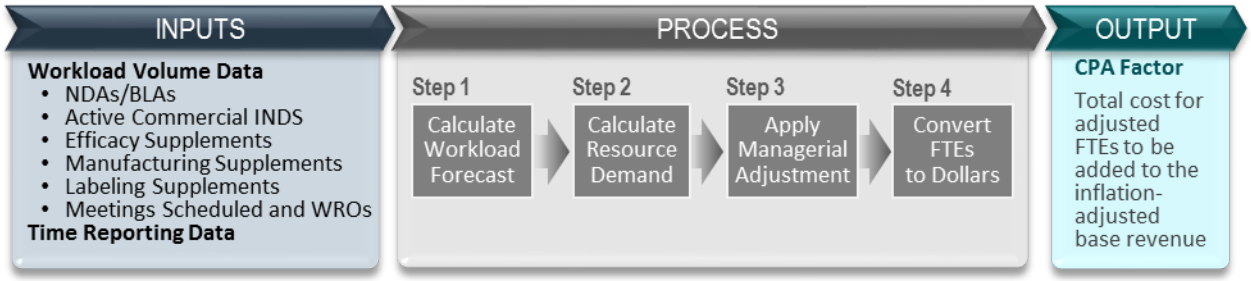

Figure 2-4: Proposed PDUFA CPA Methodology Overview

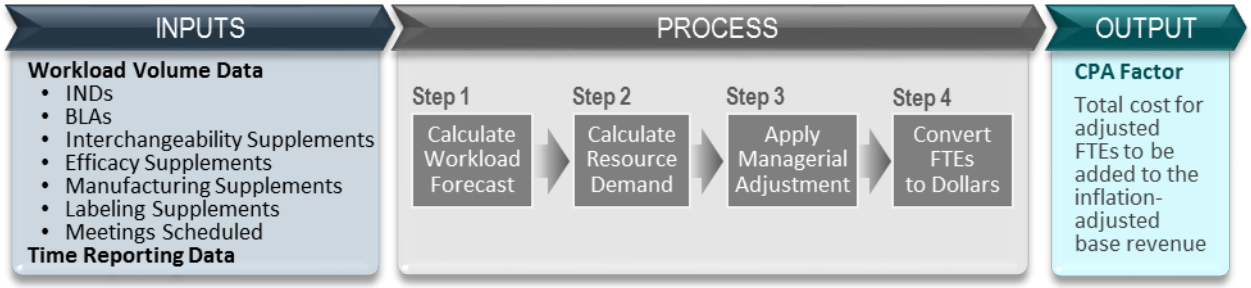

Figure 2-5: Proposed BsUFA CPA Methodology Overview

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 is to estimate the submission volume that will likely be received for the direct review submission categories outlined in Table 2-3 for the upcoming 3.5 fiscal years within PDUFA and BsUFA. 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.[10]

Table 2-3: Direct Review Submission Categories for Respective User Fee Program

Program	Submission Categories
PDUFA	Active Commercial INDs NDAs/BLAs Efficacy Supplements Manufacturing Supplements Labeling Supplements Meetings Scheduled and WROs
BsUFA	Biological Product Development (BPD) INDs BLAs Efficacy Supplements Manufacturing Supplements Labeling Supplements Interchangeability Supplements* Meetings Scheduled

*FDA included interchangeability supplements in the proposed CPA methodology. However, at the time of the current evaluation of the proposed CPA methodology, FDA had not received any interchangeability supplement submissions. As a result, FDA has not developed the initial core set of workload and resource demand forecasting models for this submission category.

[10] 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.

Step 2: Calculate Resource Demand Forecast

The second step of the proposed CPA process is to calculate the resource demand estimates for the upcoming workload associated with the direct review workload submission categories listed in Table 2-3. FDA calculates the resource demand estimate by converting the forecasted submission volume from Step 1 into resource needs measured by FTEs. FDA will analyze the historical time reporting and submission volume data to gain a macro-level view of the level of effort required for each of the direct review submission categories. Additionally, the forecast for the resource needs involved in the direct review work will 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 PDUFA and BsUFA, a difference will be determined between the estimated resource demand and current capacity for each user fee 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 is to engage in an internal structured decision process through managerial adjustments. This decision process will ensure that any fee adjustment made only reflects what can be reasonably and realistically used to support PDUFA and BsUFA. FDA will 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 need. Based on this structured decision process, FDA may make an adjustment to the resource demand FTE counts derived in Step 2 for both PDUFA and BsUFA.

Step 4: Convert FTEs to Dollars

The fourth step of the proposed CPA process is 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 uses this cost model to calculate a total cost by multiplying the adjusted total FTE count and overall cost per employee. FDA then adds this cost to the inflation-adjusted base revenue of the user fee program for reflect the changes in resource capacity needs for the process of human drug and biosimilar biological product application reviews in PDUFA and BsUFA.

3. EVALUATION FRAMEWORK

Booz Allen employed a hypothesis-driven approach to evaluate if the proposed CPA methodology represents an improvement over the interim CPA methodology in assessing FDA's resource needs with the end goal of developing a detailed report outlining findings. Multiple sources of data (e.g., methodology documentation, interviews, statutes, reports) contributed to the analysis and development of recommendations for consideration as FDA implements the methodology.

3.1 Evaluation Framework

In accordance with FDARA, the goal of this evaluation was to provide options and recommendations for the proposed CPA methodology to accurately assess changes in the resource needs of PDUFA and BsUFA. The evaluation was to occur prior to implementation of the proposed methodology and focused on a conceptual analysis to ensure that the methodology employed by FDA would foreseeably provide accurate forecasts for resource needs. Given the maturity of the proposed CPA methodology at the time of this evaluation, Booz Allen did not run any data analysis on the models. However, FDA 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 focused on whether the proposed methodology improves upon the previous methodologies and address key issues with the interim methodology. To align with documentation and forecasting practices, the hypotheses developed centered around two concepts: Key Issues and Evaluation Criteria.

Key Issues

An interim CPA methodology was employed for PDUFA while FDA developed and implemented a new and more robust methodology. FDA assessed this interim methodology to identify opportunities for improvement and was able to identify four key issues they intended to address within the proposed methodology. Table 3-1 outlines the key issues for which Booz Allen developed hypotheses to evaluate the integration of solutions proposed by FDA.

Table 3-1: Key Issues with Interim CPA Methodology

Key Issue	Description
Interim CPA methodology is a lagging indicator	The interim CPA methodology uses averages from previous years' workload submission volume, which is a lagging indicator. Lagging indicators give insights into the past however are not traditionally the best method to use for future workload. As a result of this and the time it takes to hire and train new staff, program resources are 3-4 years behind workload needs.
Interim CPA methodology does not convert submission counts into resource demand	The interim CPA methodology produced a CPA adjustment in the form of a cost percentage then added to the inflation-adjusted based revenue when setting the target revenue. This does not accurately reflect resource capacity needs in that there are no insights into how many FTEs FDA requires to meet workload demand.
Interim CPA methodology does not account for 'complexity'	Complexity in the context of FDA's RCP refers to the range of scientific and technical intricacies of human drugs. This can result in additional resource demand due to the novel regulatory issues and special considerations they require during review. The interim CPA methodology does not include a way to measure this complexity.
Commitment to support organizational review components engaged in direct review work'	The interim CPA methodology does not account for direct review submission type of labeling supplements. Per the PDUFA VI and BsUFA II commitment letters, FDA agreed that the organizations within FDA that execute the direct review work associated with the increased workload submission volume receive the funds generated from CPA.

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. This approach allowed us to assess the CPA methodology against industry-accepted qualities, but it also provided continuity in evaluating the FDA's RCP methods from previous independent assessments.[11] Booz Allen selected criteria that were relevant and realistic ways of assessing the CPA given the current phase of implementation. The development of definitions for each evaluation criteria accounted for a conceptual-level evaluation of the CPA. Table 3-2 provides details for the six evaluation criteria.

Table 3-2: 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), and results will likely be reliable and unbiased.
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.

[11] A list of related PDUFA assessments is available in Section 6.2.

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 and workload adjustment. This required us to review the past and current methodology literature, proposed CPA methodology documentation, and relevant documentation for each user fee 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 hypothesis, evaluation criteria, and key issue. Booz Allen conducted a detailed analysis, identified themes, and summarized findings and observations. Based on this analysis, we documented opportunities to strengthen the proposed CPA methodology moving forward and developed feasible recommendations to assist FDA in its further implementation.

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

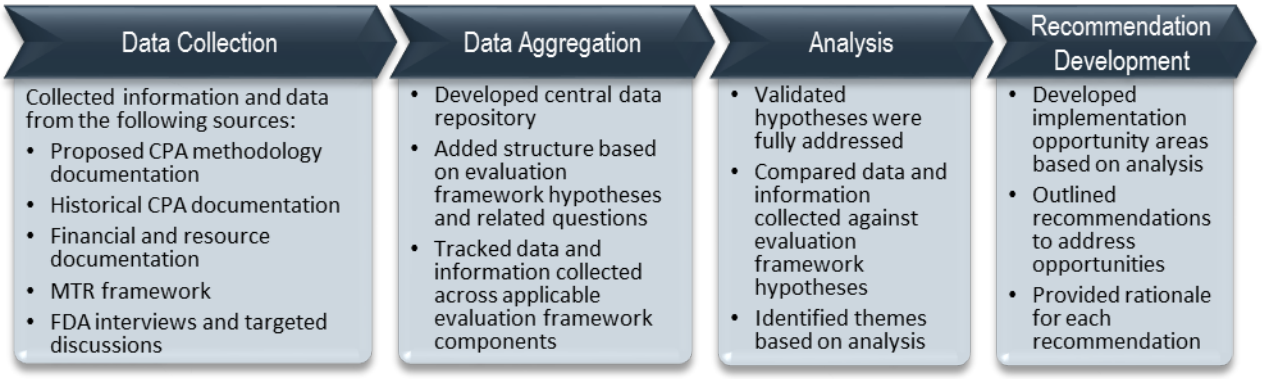

Figure 3-1: Data Collection and Analysis Approach

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

4 FINDINGS

Booz Allen analyzed data and information collected against the key issues and evaluation criteria, as outlined in the evaluation framework. By doing so, Booz Allen collected evidence to evaluate whether the proposed CPA methodology demonstrates an improvement over the interim CPA methodology to accurately assess changes in the resource needs of PDUFA and BsUFA.

Overall, FDA's CPA methodology and current implementation state of RCP and MTR align conceptually with the objective to develop a methodology to account for the sustained increases in PDUFA and BsUFA resource demand. Specifically, whether the methodology addresses the key issues and how the evidence compares to the evaluation criteria frame the evaluation. By doing this, we were able to provide a structured assessment. The sections below outline Booz Allen's findings for both the key issues and evaluation criteria.

4.1 Key Issues Findings

Based on Booz Allen's analysis, there are distinct features in the proposed CPA methodology that address key issues identified in the interim CPA methodology. Addressing these key issues improved the FDA's ability to more accurately assess changes in the resource needs of PDUFA and BsUFA. These findings related to these key features reflect the major changes in the CPA and have the greatest impact in terms of the calculations and their outcomes. Table 4-1 provides an overview of how the proposed CPA methodology addresses each key issue.

Table 4-1: Evaluation of Key Issues

Key Issue	Finding
Interim CPA methodology is a lagging indicator	The proposed CPA methodology is forward-looking by helping to estimate the likely submission volume and sustained resource demand required to support the direct review workload. FDA will build predictive models through advanced analytical techniques using multiple data sources that can be a leading indicator to estimate submission volume.
Interim CPA methodology does not convert submission counts into resource demand	The proposed CPA methodology uses time reporting data to convert estimated submission volume into resource needs by FTEs. FDA will analyze historical time reporting data and submission volume for each type of direct review workload to understand the level of effort. This level of effort helps convert the estimated submission forecasts into an estimated resource demand.
Interim CPA methodology does not account for 'complexity'	The proposed CPA methodology analyzes the historical time reporting data and submission volume which helps FDA capture a macro-level measure of complexity for each of the direct review workload submission categories. If the complexity on an average basis is increasing for any of these types of direct review workload, the time reporting data should reflect that increase in the average amount of time required per application.
Commitment to support 'organizational review components engaged in direct review work'	The proposed CPA methodology will comprehensively consider all the direct review submission categories including the labeling supplements to assess the sustained workload and resource needs of the user fee programs. The interim CPA methodology excluded labeling supplements.

4.2 Evaluation Criteria Findings

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 and provide evidence for the overarching hypothesis that the proposed CPA methodology is an improvement from previous methodologies and provides evidence that proposed methodology may accurately assess changes in the resource needs of PDUFA and BsUFA. The summary of evaluation findings in Table 4-2 describes the extent to which FDA's proposed methodology addresses the evaluation criteria.

Table 4-2: Summary of Evaluation Findings

Evaluation Criteria	Finding
Accurate	The workload forecast models will likely represent the amount of submissions FDA receives based on the approach used to predict submission volume. The proposed CPA methodology captures major types of direct review workload to measure the amount of resources needed when there are sustained increases in the workload. As the maturity of the proposed CPA methodology will grow, further evaluations will be required to see the accuracy of the workload forecast models by comparing the actuals and predicted values of the submission counts.
Adaptable	The proposed CPA methodology is adaptable to account for new and expanded data sources. This methodology utilizes OSS with R and Python that gives the flexibility of reading variety of data formats. These OSS with R and Python can also operate within different technological environments. The managerial adjustment process can help FDA account for foreseeable future business needs that may impact the CPA process.
Defensible	The proposed CPA methodology aligns to requirements set in FDARA and the PDUFA VI and BsUFA II commitment letters. FDA has developed a consensus around this methodology through a series of working groups who have domain expertise regarding the workload and resource needs for PDUFA and BsUFA. The overall CPA methodology and model development process are based on assumptions that FDA expects to remain true over time.
Efficient	FDA has plans to create a technical infrastructure that can support components related to automation and operationalization of the model development process. FDA uses existing technology for forecasting and customizes to the unique challenges that are relevant in estimating the workload level and resource needs. By customizing the use of advanced analytical techniques to help produce accurate forecasts, FDA addresses these unique challenges.

Evaluation Criteria	Finding
Feasible	The overall paradigm of the proposed CPA methodology is documented fully and outlines the steps used to calculate the CPA factor for PDUFA and BsUFA. Based on FDA's ability to build the initial core set of workload and resource demand forecasting models that use actual data, there is evidence that FDA has the tools and data sources available to begin the implementation of the proposed CPA methodology.
Meaningful	The managerial adjustment process within the proposed CPA methodology 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 potential decision factors were verified to be interpretable by the decision-makers and will likely give them relevant business insights to help make informed decisions.

The following sections provide additional details that provide context for each of the findings in Table 4-2, along with areas identified for enhancement as the proposed methodology and its inputs mature for each of the findings outlined above, along with some identified areas for enhancement as the proposed methodology and its inputs mature.

4.2.1 ACCURATE

To evaluate accuracy, Booz Allen conducted an analysis to evaluate whether workload forecast models will likely represent the amount of submissions FDA receives. In addition, we examined whether the proposed CPA methodology captures all types of direct review workload to measure the amount of needed resources.

Accuracy of Workload Forecasts

The proposed CPA methodology uses a data-driven approach to predict the likely submission volume FDA will receive as part of the direct review workload for PDUFA and BsUFA. Advanced analytical techniques through statistical analysis and machine learning are used to build predictive models to estimate the submission volume for each of the direct review workload submission categories outlined in Table 2-3. These predictive models 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 do so, FDA will create a comparison benchmark point estimate for each of the direct review workload submission categories using historical three-year average of submission volume. Each of the point estimates from advanced analytical techniques and historical three-year average will be created as of a specific date in the past. FDA will then evaluate the point estimates for accuracy using an error metric with the actual submission volume counts, in that how close are the estimated submission volume to the actual submission volume. Based on which approach gives the higher accuracy based on an error metric, FDA will use either the predictive model that uses advanced analytical techniques or historical three-year average to forecast the likely workload. FDA will perform this exercise for each of the direct review workload submission categories.

This data-driven approach using advanced analytical techniques allows FDA to be forward-looking and determine the likely amount of submissions that will be received. The predictive models will use leading indicators from internal and external data sources to help estimate the volume of submissions FDA will receive. As the proposed CPA methodology matures, it will 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 has 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 will 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

For the PDUFA and BsUFA CPA processes, the proposed CPA methodology currently captures major types of direct review workload outlined in Table 2-3 that have an associated historical submission volume to estimate the amount of workload FDA will receive in the upcoming fiscal years. FDA uses the estimated workload to then calculate estimated resource demand by analyzing the historical level of effort required per application. Based on the resource demand estimates, FDA calculates additional resource needs within the current capacity of the PDUFA and BsUFA. Although FDA includes the major types of direct review workload in this process, there are other types of work such as post-market safety and some subsets of policy and guidance development to potentially consider as direct review work and incorporate in the future iterations of proposed CPA methodology.

4.2.2 ADAPTABLE

Booz Allen evaluated whether the methodology can scale to include further refined data in terms of new data sources, expanded data sources, and technological environment. We also assessed how the methodology accounts for foreseeable future business needs (e.g., requirements, commitments, priorities).

Adaptability in Data and Technology

The proposed CPA methodology is adaptable and can account for new and expanded data sources. FDA uses advanced analytical techniques to analyze internal and external data sources to forecast submission volume. These advanced analytical techniques can support inclusion of other data sources. Additionally, the proposed CPA methodology utilizes OSS with R and Python that have existing libraries. These libraries can provide the flexibility to read data in variety of formats that include structured, unstructured, and semi-structured data. Analysts are continuing to keep track of potential additional data sources to include for future model development activities. These OSS with R and Python can also operate within different technological environments such as cloud and on-premise technical infrastructure.

Foreseeable Business Needs

FDA is exploring how to best structure the managerial adjustment process to make the most informed decision. In doing so, the proposed CPA methodology could account for foreseeable future business needs using the managerial adjustment process. The managerial adjustment process 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 managerial adjustment process has the potential to consider qualitative factors such as future program requirements, commitments, and priorities.

4.2.3 DEFENSIBLE

Booz Allen evaluated whether defined objectives and methodology align to requirements. We also assessed whether the methodology and its rationale are clearly documented and/or communicated and if the methodology was based on assumptions that are reasonably expected to be/remain true.

Requirements

The proposed CPA methodology aligns to requirements set in the PDUFA VI and BsUFA II commitment letters. These commitment letters outline that the FDA will implement robust methodologies for assessing resource needs of PDUFA and BsUFA to account for sustained increases in workload. FDA staffed a cross-collaborative team comprised of workload and resource demand forecasting experts to meet the requirements set forth by the commitment letters. This cross-collaborative team used best practices within data science framework 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 were iterative in nature and the team will continue to explore how to make the proposed CPA methodology more robust.

Clarity of Methodology and Rationale

FDA has developed a consensus around its proposed CPA methodology through a series of working groups who have domain expertise regarding the workload and resource needs for PDUFA and BsUFA. FDA discussed the steps used to calculate the workload and resource needs internally through routine meetings among the cross-collaborative team comprised of forecasting experts. These meetings helped create a logical progression of steps that align with business experience and expected outcomes. FDA also held peer reviews throughout the model building process in which analysts presented findings, provided updates on the evolution of models over time, and evaluated model soundness from a technical perspective to ensure that FDA analysts can reproduce models over time. Individual analysts created technical appendices that document each predictive model to estimate the submission volume for each of the direct review workload submission categories. The appendices outline unique assumptions, data collection and integration, advanced analytical techniques used for model development, and planned future refinements. However, additional clarity behind the rationale on the modeling decisions to date will be helpful to serve as a baseline as the methodology matures.

Assumptions

FDA included model development process assumptions within the technical documentation for each of the predictive models built to estimate the workload level and resource needs for the initial core set. In addition, there were high-level assumptions for the proposed CPA methodology that involved accuracy in time reporting data, the performance of model, and how the methodology will improve over time. 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 their rationales as to why they are reasonably expected to remain true.

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 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 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 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.

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 process for model development for forecasting can be automated and whether there are plans to use existing technologies for forecasting. We also evaluated whether any complexities and customizations in the methodology exist to generate better outputs.

Automation

Within the proposed CPA methodology, FDA can automate the process around model development that includes data extraction and operationalizing the models. Currently, FDA extracts data from internal and external sources using manual data queries, web scraping techniques, and Application Programming Interface (API) calls that serve as an input for the workload and resource demand forecasting models. Efforts are currently underway to automate extracting these data inputs for the predictive models. FDA has also created a vision for the technology infrastructure that can help support the technical elements in the proposed CPA methodology. To date, FDA has gathered a preliminary set of technical requirements for a production environment from the workload and resource demand forecasting teams. These requirements outline the storage, computational, and visualization capabilities needed to run and further explore the workload and resource demand forecasting models. In addition to the technical requirements, FDA has developed a preliminary logical data model. This data model outlines all the currently used data sources, key attributes, and key relationships to support the workload and resource demand forecast modeling efforts. FDA will continue to update both the technical requirements and data model as modeling efforts progress. This technology infrastructure will allow FDA to transition into a cohesive and streamlined platform that considers efficiency, reusability, scalability, and stability as the primary drivers.

Use of Existing Technology

The proposed CPA methodology uses existing technologies through OSS with R and Python for workload and resource demand forecasting. These technologies have existing libraries used for statistical analysis, machine learning, and mathematical operations that a community of industry experts builds, reviews, and manages. By using the statistical analysis and machine learning libraries, FDA can start with a foundation for how to conduct workload forecasting and customize it to the unique challenges that are present in predicting the submission volume. The mathematical operations will allow FDA to analyze the historical level of efforts in time reporting data for each of the direct review workload submission categories and calculate the amount of additional resources required for PDUFA and BsUFA.

Complexity and Customizations

FDA customizes the use of advanced analytical techniques for developing predictive models to the unique challenges that are present in estimating the submission volume for each of the direct review workload submission categories. These unique challenges included how to generate certain submission types due to the nature of the medical product lifecycle and the sometimes-limited historical submissions data. The overarching principle used in the modeling efforts was to reduce the error metrics of advanced analytical techniques and outperform the error metrics associated with the benchmark of the three-year average of submission volume. FDA analysts involved in the model development process achieved this objective by creating and testing multiple predictive models to meet the unique needs of estimating each of the direct review workload submission categories. Based on the model performance results, FDA chose a model with the smallest error metric for estimating the submission volume of each submission type. These predictive models then went through a peer review process to ensure that each addressed the business question at hand and technical soundness of the models. FDA analysts tracked 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 are, or will be, available, as well as whether standardization of the methodology allows for replication and maintenance in the future. In addition, Booz Allen evaluated whether the models can be feasibly trained on the incoming data.

Tools and Data Sources

Based on FDA's ability to build the initial core set of workload and resource demand forecasting models that use actual data, there is evidence that FDA has the tools and data sources available to begin the implementation of the proposed CPA methodology. The submission volume and time reporting data are currently available and could be feasibly employed in the predictive models to estimate the submission volume and resource needs for PDUFA and BsUFA. In addition, FDA has utilized current tools and technologies to run these predictive models. FDA demonstrated that the proposed CPA methodology can feasibly be trained on the incoming data. FDA used both internal and external data sources to identify the leading indicators that help estimate the submission volume for each of the direct review submission categories. These internal and external data sources contained dictionary and appropriate documentation to help give insights into each variable and how to effectively use them. Within this process, FDA has confirmed data quality monitoring and processing measures are in place for all internal sources of data.[12]

Methodology Standardization

The overall paradigm of the proposed CPA methodology is documented and outlines the steps used to calculate the CPA factor for PDUFA and BsUFA. FDA fully documents the overall paradigm of the proposed CPA methodology and outlines the steps used to calculate the CPA factor for PDUFA and BsUFA. The implementation of initial core set of workload and resource demand forecasting models along with the documentation created will likely allow for maintenance and replication of the methodology at a conceptual level. However, the managerial adjustment process, and converting adjusted FTE counts to actual costs, could benefit from additional process details. FDA is currently planning to formalize these processes prior to the implementation of the proposed CPA methodology.

4.2.6 MEANINGFUL

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

Interpretability and Utility

At the time of this assessment, FDA was still developing and validating managerial adjustment process. The managerial adjustment process within the proposed CPA methodology will potentially look at additional information related to the 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. FDA decision-makers verified these potential factors to be interpretable and that they provide relevant

[12] An analysis of the data quality process was not in-scope for this evaluation.

business insights to help make informed decisions. The outputs of the models and additional information aligned with what key factors decision-makers would need when making decisions on FTEs requirements to meet workload demand. 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.

5 RECOMMENDATIONS

Booz Allen identified five potential actions through evaluation of the data for FDA to consider as they implement and refine 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.

Booz Allen developed a series of recommendations that 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 along with the evaluation criteria impacted. FDA should evaluate if and when these recommendations should be incorporated into the CPA methodology over the course its implementation. The intent is not to suggest that the recommendations require immediate action.

Table 5-1: Summary of Recommendations

Recommendation	Relevant Evaluation Criteria
Prediction Interval: 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
Related Direct Review Workload: FDA may want to perform data exploration that analyzes how other types of direct review work, such as post-market safety and some subsets of policy and guidance development, could be incorporated into the methodology, which will enhance the accuracy in resource demand forecasts.	Accurate Adaptable
Managerial Adjustment Process: FDA may continue refining the managerial adjustment process 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.	Accurate Meaningful
Methodology Documentation: FDA should consider including the overall methodology assumptions, rationales, and procedures in related documentation to help 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 Prediction Intervals

As the methodology matures, 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 further meaningful outputs to the decision-makers involved in the managerial adjustment process.

5.2 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 outputs and the application of what-if business scenarios may help provide additional meaningful outputs to the decision-makers involved in the managerial adjustment process. This may enhance the accuracy of the adjustments to the resource demand forecasts during the process as well.

5.3 Related Direct Review Workload

As the methodology continues to iterate yearly, FDA may want to perform data exploration that analyzes how to incorporate other, more complex types of direct review work, such as post-market safety and some subsets of policy and guidance development, into the workload and resource demand forecast models. Currently, FDA includes all the major submission types in the workload forecast models. However, FDA may want to explore expanding these models to reflect additional workload that may not tie directly to these major submission types. The main objective of the CPA process is to adjust the annual target revenue of PDUFA and BsUFA to reflect changes in resource capacity needs. Each FDA office that is involved in direct review has allocated resources to perform work for meeting the performance goals listed in the commitment letters. Data exploration will help FDA identify how to incorporate these additional complex types of potential direct review work that the proposed CPA methodology does not capture currently. By adapting the methodology to include other types of direct review work, this may allow FDA to calculate any additional resource needs with further accuracy.

5.4 Managerial Adjustment Process Refinements

As the methodology matures, FDA will continue refining the managerial adjustment process. Below are 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, 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 to ensure 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.

These suggestions may help provide additional meaningful outputs to the decision-makers involved in the managerial adjustment process. This may enhance the accuracy of the adjustments to the resource demand forecasts during the process as well.

5.5 Methodology Documentation

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

- The overall methodology assumptions, similar to what was done in the technical documentation for the model development process. 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.
- Rationale for decision-making in the model building process. Historical documentation of the rationale will support FDA with future analysis that enhances efficiency by providing a baseline for the needed revisions. Since FDA will iterate the proposed CPA methodology yearly, understanding the reasons behind the process will help to interpret the unique aspects of models built for each of the direct review workload submission categories. By documenting the rationale behind decisions made, future iterations of the model development can utilize this information to help make continuous improvement. Rationale also supports the justification of each model's creation to support a transparent process and helps with knowledge transfer.
- Standard operating procedures to promote replicability and transparency.

By creating this documentation, the overall CPA methodology will be more defensible because there are clearly defined assumptions, rationales, and procedures. In addition, the documentation can create transparency and enhance 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
API	Application Programming Interface
BLA	Biologics License Application
BPD	Biological Product Development
BsUFA	Biosimilar User Fee Amendments
CPA	Capacity Planning Adjustment
FD&C Act	Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FDARA	FDA Reauthorization Act
OSS	Open-Source Software
FTE	Full-Time Equivalent
FY	Fiscal Year
IND	Investigational New Drug
NDA	New Drug Application
NME	New Molecular Entity
PDUFA	Prescription Drug User Fee Act
MTR	Modernized Time Reporting
RCP	Resource Capacity Planning
SME	Subject Matter Expert
WRO	Written Response Only

6.2 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	PDUFA User Fee Rates Archive	8/8/2018
3	BsUFA User Fee History	8/1/2018
4	Resource Capacity Planning and Modernization Time Reporting Implementation Plan	3/2018
5	PDUFA V Workload Adjuster Evaluation Final Report	9/24/2015
6	Evaluation of the Adjustment for Changes in Review Activities Applied to the Prescription Drug User Fee Act (PDUFA) IV Workload Adjuster for FY 2009	3/31/2009
7	Review of Biosimilar Biologic Product Applications: Study of Workload Volume and Full Costs - Interim and Final Report	3/23/2018
8	User Fee Financial Reports	3/28/2018
9	User Fee Performance Reports	3/29/2018
10	User Fee Five-Year Financial Plans	5/31/2019