UNITED STATES FOOD & DRUG ADMINISTRATION

_____

Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments

_____

DATE: Monday, June 22, 2020

TIME: 9:00 a.m.

LOCATION: WebEx Meeting

REPORTED BY: Irene Gray, Notary Public

JOB No.: 4131923

A P P E A R A N C E S

Monica Ellerbe

Jay Tyler

Robert Marcarelli

Josh Barton

Athena Tang

Kendra Orjada

P R O C E E D I N G S

MONICA ELLERBE: Good morning, everyone. My name is Monica Ellerbe, Director of Business Management Services in the Office of Operations, Office of Finance, Budget & Acquisitions in the FDA. Welcome to this year's public meeting on financial transparency and efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic User Fee Amendments.

At this time, Jay Tyler will continue with the welcome and overview of today's meeting.

MAN 1: Jay, you may have yourself muted on your phone.

JAY TYLER: Apologies. Technical challenges here. I'm going to start over. Thank you, everybody, for joining. Can you hear me?

MAN 1: Yes, we can hear you, Jay.

JAY TYLER: All right, let me try this again. Thanks for joining, everybody, and I specifically want to thank you for your flexibility in joining virtually given the public health crisis that continues to face the globe by the pandemic. My name

is Jay Tyler. I'm the CFO of the Food & Drug Administrator. And, again, apologies for technical difficulties. I thought I was off of mute but was not.

This is, of course, a follow-up meeting to the annual meeting, first annual meeting that we had last year where we are responding to FDA commitment under PDUFA VI, CFO II, and PDUFA II to enhance transparency and manage our user fee resources.

Last year, the meeting covered the findings and FDA's response to the third party evaluation of user fee program resources at the FDA. This year, the FDA is excited to provide an update on the significant amount of work that we have accomplished in furthering our administration of our user fee resources in an efficient manner. I want to cover the agenda today. Next slide.

So, on the agenda today, we have Rob Marcarelli from my office, the office of Finance, Budget & Acquisitions, who'll provide an update on the five-year plan. So, PDUFA, BsUFA and GDUFA. Josh

Barton, the Director of Cedars Resource Capacity Planning Team, and he will provide an update on the implementation of the resource capacity plan capability and introduce the capacity planning adjustment methodology.

Athena Tang and Kendra Orjada from Booz Allen Hamilton will provide a summary of the findings from the capacity planning adjustment evaluation. I will provide an update on the progress we have made toward implementing the recommendations from the user fee financial management evaluation that was conducted last year. And as communicated in their FR notice, you will have an opportunity to provide public comment to the FDA at the end of the meeting.

You will submit comments through your chat function. Your comments will be documented as part of the public record. There is also a public docket open until July 20th to which the public can submit comments. So, without further ado, I'll turn it over to Rob, who'll provide an update on our five-year plan. Rob?

ROBERT MARCARELLI: Thanks, Jay, and

good morning, everyone. My name is Robert Marcarelli from FDA's Office of Finance, Budget and Acquisitions. I will be providing an update on the human drug user fee five-year financial plans. Next slide. Thank you.

In FY2019, FDA had net collections of 1.015 billion in prescription drug user fees, spent 1.017 billion for the human drug review process, and carried a cumulative balance of 220 million forward for future fiscal years.

In PDUFA VI, FDA is implementing numerous commitments made under the user fee agreement as well as new programs mandated by Congress and the FDA Reauthorization Act of 2017 or FDARA. FDA's continuing to make significant progress implementing important PDUFA VI commitments including enhancing patient input and integrating it into regulatory decision making, enhancing regulatory science and use of real world evidence, expediting drug development, enhancing benefit risk assessment and regulatory decision making, enhancing regulatory decision tools to support drug development, reviewing, enhancing and

modernizing the FDA drug safety system, and improving the efficiency of human drug review to require electronic submission and standardization of electronic drug application data.

Additional commitments made in PDUFA VI includes an expansion of the Patient-Focused Drug Development Program, enhancements to FDA's management of combination products, new programs related to complex innovative trial designs, model-informed drug development, and exploring the use of real world evidence to support regulatory decision making, including approval of new indications of approved drugs.

FDA is also committed to the Regenerative Medicine Advanced Therapies Program designated by the 21st Century Cures Act, which facilitates development of PDUFA regenerative medicine products. Recently, FDA embarked on an initiative to modernize the New Drugs Regulatory Program and will continue its modernization over the course of PDUFA VI. These changes are intended to fee up resources so that our scientists have more time to focus on drug

development, particularly for unmet medical needs, and on the multiple collaborations needed to make candidate drugs -- are developed and assessed properly with appropriate input from external scientists, expert physicians and patient communities.

The initiative includes regulatory and review process changes as well as organizational restructuring. FDA also intends to strengthen the institutional support structures, including personnel and information technology that underpin the regulatory process. The initiative highlights the following strategic objectives:

Recruiting the best and brightest individuals to promote scientific leadership; enhancing FDA’s focus on interdisciplinary teams; prioritizing operational excellence and improving knowledge management; emphasizing the importance of safety across a drug’s life cycle and incorporating the patient’s voice in regulatory decision making.

The changes to the PDUFA VI fee structure are improving the predictability of FDA funding, maximizing efficiency by simplifying the

administration of user fees and enhancing the flexibility of financial mechanisms to improve management of PDUFA program funding.

In FY 2019, FDA collected 100.5 percent of the plan target revenue, and through the first two years of PDUFA VI, FDA has collected 100.1 percent of the total plan target revenue.

FDA's focus over the remainder of PDUFA VI is to ensure there is enough resource capacity to manage the program workload, meet performance and procedural goals, and deliver on commitments funded in PDUFA VI.

In FY 2019, FDA continued to make investments in the PDUFA program to ensure that it is continuing to operate on a strong foundation, to deliver on its PDUFA VI commitments, and to modernize to meet evolving workload demands and scientific innovation.

These investments were made in areas including premarket review, post-market safety including investments and the Sentinel Initiative and the FDA Adverse Event Report System, and NIT.

Additional information is available in the FY ’19 PDUFA financial report and the FY ’20 update to the PDUFA five-year plan. Next slide, please.

In FY 2019, FDA had net collections of 35 million in BsUFA fees, spent 42 million in user fees for the BsUFA program, and carried forward a cumulative balance of 32 million for future fiscal years. BsUFA II focuses on ensuring effective scientific coordination and review consistency through review, procedural and meeting performance enhancements.

FDA’s commitments also include enhancing capacity for guidance development in specified areas and expanding review staff capacity and training. As part of BsUFA II, FDA will continue to facilitate the development of biosimilar biological products, including interchangeable biosimilars through the strategic development of FDA’s Biosimilar Biological Product Review Program, and through an ongoing clarification of the approval pathway of these products.

FDA recently developed the Biosimilars

Action Plan, BAP, which advances policies to facilitate the efficient development and review of biosimilar biological products. FDA continues to effectively allocate its fiscal and human resources to support these priorities and advance challenges and opportunities for the continued development of FDA's Biosimilar Biological Product Review Program.

The deliverables described in the BAP are in various stages of progress and many of the deliverables have been accomplished. This plan aligns with FDA's strategic priorities and reflects FDA's commitments in the BsUFA II goals letter: Innovations in regulatory science and expanded opportunities for collaboration.

To better support these objectives, FDA transitioned the therapeutic biologics and biosimilar staff to the Office of Therapeutic Biologics and Biosimilars or OTBB in 2019. The establishment of OTBB is intended to improve coordination and support of all activities under the BsUFA program, accelerate responses to stakeholders, and support efficient operations and policy development. The agency intends

to utilize user fee resources, including the carryover balance to fulfill these priorities, build staff capacity for OTBB, launch the new scientific staffing capability to enhance hiring and retention, and implement relevant portions of the 21st Century Cures Act.

Other OTBB ongoing activities include the development and implementation of new FDA review tools, including standardized review templates, the publication of a timely guidance for sponsors to provide scientific and regulatory predictability, and the modernization of the Purple Book to include more information about licensed biological products.

FDA's focus over the remainder of BsUFA II is to continue building enough staff capacity to develop on program performance and procedural goals, as outlined in the BsUFA II commitment letter. Additional information is available in the FY 2019 BsUFA Financial Report and the FY '20 Update to the BsUFA Five-Year Financial Plan. Next slide, please.

In FY 2019, FDA had net collections of 497 million in human generic drug user fees, spent 465

million in user fees for the human generic drug review process, and carried a cumulative balance of 204 million forward for future fiscal years. Under GDUFA II, FDA continues to modernize the generic drug program by improving the program's efficiency, quality and predictability.

With the goal of increasing consumer access to safe, high-quality, and affordable generic drugs, GDUFA II focuses on two major objectives: Reducing the number of review cycles to approval, and increasing the approvals of safe, high quality, lower cost generic drugs.

The program now has different review goals for priority applications and more communications touchpoints with industry. GDUFA II establishes a well-organized process to review complex drug products more efficiently. This approach allows FDA to work closely with the generic drug industry by allowing earlier and more frequent meetings between FDA and the applicant. Challenges that arise during the development of these products can be forecasted and addressed in an efficient and effective manner.

FDA Will continue to expand upon improvements made in the following areas in GDUFA II: Enhancement of development and review of hard to genericize complex products. FDA will continue to implement and enhance the Pre-ANDA Program for complex products, which features new product development, pre-submission, admin review cycle meetings to help clarify regulatory expectations early in product development and during application review.

Continued enhancement of business processes to increase first cycle approvals and reduce the time to approval by increasing communication and collaboration between FDA and industry. FDA will continue to enhance the controlled correspondence process that allows generic drug developers to ask questions prior to ANDA submission.

FDA will continue enhancements to mid-cycle communications during the review of an original ANDA when further information or clarification is needed or would be helpful to allow completion of FDA’s review. These enhancements will include the development of tools that help improve the quality of

submissions and identify earlier in the process potential issues that could impact approval of an application. Also, implementation of FDA's Drug Competition Action Plan, which focuses on developing and implementing general policies to further expedite the availability of generic drugs.

FDA will continue to work to improve the efficiency of the generic drug development review and approval process. FDA will continue its efforts to maximize scientific and regulatory clarity with respect to complex drugs. FDA will also continue to work to close loopholes that allow brand name drug companies to game SCA rules and ways that delay the generic competition Congress intended.

Under GDUFA II, FDA committed to advance scientific efforts to develop new human generic drug products and novel dosage forms. Through its regulatory science initiatives, FDA continues to work on developing tools, standards and approaches to assess these products and facilitate the path to market approval. One example of FDA's commitment to this program has been its product-specific guidances

and recommendations for regulatory submissions. For example, ANDA's Pre-ANDA meeting requests and controlled correspondence.

These product-specific guidances have provided industry with draft recommendations on the design of bioequivalent studies and scientific advice pertaining to finished dosage forms and drug substances or active pharmaceutical ingredients that can be used in the development of generic complex and noncomplex drugs.

In addition to serving as the scientific basis for the development of product-specific guidances and specific pre-ANDA communications, research outcomes are published in the peer-reviewed scientific literature presented and discussed at major medical and scientific meetings and contributed general guidance development.

As part of the GDUFA II commitments, FDA posted its GDUFA science and research outcomes. This website provides a list of all the research outcomes for the fiscal year in one easily accessible place and fulfills the commitment to annually report

the extent to which GDUFA regulatory science-funded products support the development of generic drug products, the generation of evidence needed to support efficient review, and timely approval of ANDAs, and the evaluation of generic drug equivalents.

These outcomes are also included in the GDUFA Science and Research Report. The website and report provide greater transparency regarding the important work the General Drug Program engages in advanced -- engages in to advance the science of generic drugs and provide generic drug developers, applicants and FDA reviewers essential tools and information to keep expedite -- to help expedite the availability of high-quality, lower cost, safe and effective generic drugs.

FDA is assessing opportunities to invest GDUFA resources including the carryover balance to support the program. FDA's focus over the remainder of GDUFA II is to continue to strive to hire scientific and regulatory staff while also making targeted strategic investments to enhance productivity, support regulatory science and policy

efforts, and ensure the availability of effective generic drug products.

(Audio Breaks Up)

-- will provide an update on resource capacity planning implementation. Next slide.

JOSHUA BARTON: Hi, good morning. This is Josh Barton, Director of our Resource Capacity Planning Team here in CDER. And I'm assuming that you can hear me. If so, can we go to the next slide? All right, perfect.

All right, so this morning, first of all, I want to say thank you to everyone for being able to join us this morning, and especially to Monica and her team for helping to enable the technology for this meeting. I'm going to speak -- I'm going to give a quick update on the implementation of our resource capacity planning capabilities, and then I'll speak to the new capacity planning adjustment methodology. Next slide.

All right, first, a little bit of background on our resource capacity planning commitments. As you may be well-aware, as part of

PDUFA VI, BsUFA II, and GDUFA II, the FDA committed to modernizing our activity based time reporting practices and to building our resource planning capability, which we call RCP.

The capabilities would provide FDA with the tools to better understand its future resource needs and to adjust internal operations to meet the expected workload. In addition, there was a recognition and a process established in statute that these two capabilities, when established, would provide the FDA with the data to better inform the more optimal capacity planning adjustment methodology, which is used to help set the annual target fee revenue for PDUFA and for the first time for BsUFA. Next slide.

There are a number of specific commitments listed in the commitment letters. We published our implementation plan back in 2018. We've built a staff to implement and manage the RCP implementation, which includes the establishment of a team in headquarters to lead inside time reporting implementation. And this past year, the third party

assessment to recommend new methodologies to adjust the fee revenue amounts based on resource needs was completed for PDUFA and BsUFA. That study was published at the beginning of April and there was a docket open that closed in May.

And, as mentioned, the statutory process -- the process outline and statute, after review of public comment on this report, the FDA made out the new revenue adjustment methodology for PDUFA and BsUFA. And you will hear more about the evaluation findings after I'm done. Next slide.

This -- you may have seen before if you've joined us previously or read our implementation plan -- this is a visual we use to help describe the long-term vision and approach for implementing capacity planning capability. One of the key takeaways here is it does take time to fully implement and mature capability of this kind. So, we've really been focused on establishing a foundation, which includes the implementation of 100 percent time reporting, establishing the initial resource forecasting algorithms, the initial data structure and

enabling the fee setting with the capacity planning adjustment methodology.

We've also begun to work towards Phase II, building a support model and organizational design. This is really to help ensure that we align around with working to integrate RCP outputs with internal business processes and really supports this sustainable RCP capability.

Phase III is focused on implementation of the closed loop planning capability. So, this includes a more refined ability to validate and refine our algorithms and to improve our ability to adjust and manage our capacity, as needed.

Phase IV and V are really more part of the longer-term potential vision where the tools developed and the data analysis developed could be further integrated with other internal systems use and support, workflow management, projects management and portfolio analytics and reporting. But those are longer term prospects to be considered at a future point. Next slide, please.

So, real quick, what is resource

capacity planning? This is our very simple high-level way -- slide that we use to describe capacity planning. We really see this as enabling an ability to identify the resources that are needed for our programs before they are needed. And this is really a function of our review timelines as well as the time required to hire and train new review staff.

So, we are seeing -- if we are experiencing a large increase in work received today, there's limited ability to hire additional staff in the time needed to review any new applications. So, we really need to get ahead of the curve and understand what is happening in the industry and how that's likely to translate into regulatory submissions and work for the agency over, roughly, a 2-3 year horizon.

So, the way we approach that, we have three major work streams. One being the time reporting, which provides us with better data on the level of effort; we have our workload forecasting work stream, and this is the development and implementation of advanced predictive analytics to forecast the

likely incoming work; and then our resource forecasting work stream pulls together those two data inputs and translates likely resource needs into FTE requirements.

So, if we were to forecast hypothetically that we were expecting 10 percent more NDAs next year, the resource forecasting work stream would help, using the time reporting data to establish some algorithms. We'll then translate that 10 percent more NDAs into X number of medical officers, X number of biostatisticians, etc.

The way that these resource forecasts can be used include balancing our existing capacity and prioritizing our existing resources internally, supporting the revenue adjustments, specifically with PDUFA and BsUFA, helping to inform more proactive hiring plans and to help inform more accurate financial forecasting. Next slide.

So, our near term implementation timeline, we have built our foundational capabilities, which includes the time reporting and the methodology for resource capacity planning. Ongoing, which will

always be ongoing, are continued operationalization of the RCP capabilities, and this ensures ongoing management of the time reporting as well as ensuring time reporting compliance and accuracy across the enterprise; as well as operationalizing our predictive models and algorithms to produce our resource forecast.

Next steps in terms of helping to establish and develop the sustainable and scalable support system includes developing a technical infrastructure to enhance automation and replicability of the analysis and reporting, and considering, where applicable, expansion to -- of these capabilities to other centers, as appropriate, and really gaining support by the enterprise-wide implementation, as appropriate. Next slide, please.

Milestones to date. We've established the time reporting with CDER and CBER. So we have over 6,000 employees of reporting time year round within those centers. We -- the inside time reporting has also recently been implemented in CDRH as well as the Oncology Center of Excellence. We've achieved at

least 95 percent center-wide compliance across the centers and have established interactive dashboards and visualizations to help support leadership decision making.

We designed our predictive models for incoming regulatory submissions, including models to predict future submissions, including INDs, NDAs, BLAs, various supplement types, formal industry meetings, and improved upon the previously utilized three-year average methodology employed in the capacity planning adjustment methodology for PDUFA.

We developed future-looking resource forecasts including creating continuous forecast resource algorithms utilizing the time reporting and developed resource algorithms across CDER and CBER. Next slide, please.

So, the RCP capability will help enhance the way that FDA operates. So, the RCP capability really helps to establish an organization -- and sets the organization up for a more structured data-driven approach to operational and resource decision making. So, this helps to enable more

proactive resource planning, including central reprioritization of work and resources, as well as targeted hiring plans based on workload forecast.

It helps enable an approved user fee setting methodology, which I'll discuss over the next couple of slides, including a data-driven, target-revenue adjustment process, including the ability to incorporate increases in submission complexity into future iterations of the adjustment, and helping -- using the forecast to help provide foundational data for updating of things like the five-year financial plan.

This also helps to enable enhanced management of financial resources, including increased visibility to future resource needs to inform budget and tracking of forecasted financial needs versus actuals. Next slide.

All right, so now I'm going to transition to speaking about the capacity planning adjustment methodology for PDUFA and BsUFA. First, why -- why are we looking at a new investment methodology? The new fee-revenue setting methodology

improves upon well-established issues with the existing interim capacity planning adjustment by developing a forward looking approach.

So, the current -- and this is just speaking to PDUFA, since BsUFA has not had an adjustment thus far -- but the current -- the interim capacity planning adjustment for PDUFA utilizes a lagging indicator, which are three-year averages. So, therefore, it compensates the agency for increases that occurred in the past. It's based on submission counts, and timing is compounded by hiring timeframes.

The future state adjustment is forward-looking, so it compensates for likely increases, it translates submission activity to likely resourced demand. So, again, like I'd said earlier, if we are expecting 10 percent more NDAs, what does that mean in terms of FTEs by type? And by being forward-looking it helps to better time resources to account for the hiring and training timeframes.

The graph on the bottom, it's a little bit dated but it still explains the concept. The example -- the bars are active commercial -- I'm

sorry, commercial INDs with activity in PDUFA. And you can see that there's a pretty strong trend, upward trend. When the example here is from FY '18 fee setting, so when fees were set in FY '18, this utilized a three-year average as of FY '17. So, you can see that's always a little bit behind the curve.

And then once those -- that adjustment occurs, it still then takes time to hire and to train review staff. So, given over that time period work is likely to have increased further, there's always a structural gap with the current state adjustment.

So, the idea of the future state is we're trying to get ahead of that curve and adjust to account for these timing issues, so that we can actually have a more optimal level of staffing at the time that we need the staffing to deliver on our review timelines and public health mission. Next slide, please.

So, this is an overview of the new capacity planning adjustment approach. It has four major steps: The first is to forecast submission volume; the second is to calculate future resource

forecasts; the third is to assess the feasibility of acquiring the needed resources; and the fourth is to convert the adjusted FTEs to dollars. So, I'll take these one by one in a little bit more detail.

Step One, forecasting submission volume. So, this is, again, using the predictive -- the advanced analytics to predict the volume of submissions by submission type. So, for the capacity planning adjustment methodology we are using commercial INDs, original NDAs, BLAs, supplements, including efficacy labeling, manufacturing supplements and industry meetings.

For PDUFA, for BsUFA we're using BPDs instead of commercial INDs. And, of course, we just have 51 KBLAs instead of original NDAs and BLAs. Otherwise, the approach is the same.

If you're familiar with the interim PDUFA methodology, these are the same inputs for PDUFA with the exception of labeling supplements, which is the only new addition to the methodology at this point. And when we were talking about industry meetings, for PDUFA that includes your Type A through

C meetings, including written response only, and your Type 1 through 4 meetings for BsUFA.

So, first, we forecast the likely volume for the submission types. And the second step is to calculate the future resource forecast. So, those are the FTE algorithms which are informed by the time reporting data and, again, that translates the volume of expected work into FTE demand.

Step 3, assessing the feasibility of acquiring the needed resources. This is a completely new aspect of the methodology. This is a structured internal decision process to compare the forecasted FTE resource demand versus the current existing capacity. And then to consider whether -- whether that delta needs to be adjusted to ensure that any fee adjustment is made only for what is needed and what can realistically be utilized.

So, again, this is a structured internal decision process really to make sure that if there is an adjustment to the fee amounts, it can really be utilized to support the program in the intended way and to bring on the additional FTEs that

are needed, if they are needed. So, if you can indulge a somewhat hyperbolic example with made-up numbers. Say, hypothetically, a program were to forecast the need for 500 additional FTEs. Again, made-up numbers. But based on our experience with hiring and attrition over the last few years, bringing on an additional 500 FTEs is unrealistic in one fiscal year.

So, then we would, through the structured decision process, for example, we would then adjust that number down to an amount that is more realistic and can actually be brought onboard within the fiscal year. In addition, we'd look to see what other resources -- what other financial resources, if any, might be able to support any additional needed FTE resources before implementing an adjustment to the fee amounts.

So, Step 4 is converting any adjusted FTEs into dollars. So, this is just taking the adjusted, reasonable and realistic FTEs needed and applying an FTE cost from the FTE cost model to that amount. That's a little bit more straightforward and

transparent than the methodology used by the interim capacity planning adjustment. If you're familiar with that, you know that that produces, at the end of the day, a percentage, and that percentage is then added to all of our inflation-adjusted target revenue, which is a little bit harder to explain exactly what is happening. So, by taking the FTEs and multiplying that by the FTE cost, this should be more straightforward and transparent of what dollars are being added and for what. And next slide, please.

So, next steps. We're really working to full enable our RCP capabilities. As noted earlier, it does take -- it does take time to implement and mature these capabilities. The foundational capabilities have been built but there are opportunities to further develop and improve over time.

This includes continual improvement of our predictive models and resource algorithms, which will always be an ongoing aspect of the program to ensure that our models are as -- are predictive models perform as optimally as possible. This includes

integrating additional data sources into work with models for enhanced accuracy; maintaining high levels of compliance and accuracy in the time reporting; and considering additional drivers of effort to include into the resource forecasting algorithms, as well as expansion to other types of direct review work, including, for example, areas like post-market safety.

Building and maintaining the technical environment to support the RCP operationalization. So, I spoke to this a little bit earlier. Really ensuring -- you know, we've built the analysis and we're really looking to industrialize the IT to support that in an optimal manner. So, creating that IP environment, historic foundational data in a centralized location, enabling advanced analytical capability to more automate the run of predictive models and the resource algorithms and lower the manual effort required to implement those; and enhance the visualization and reporting of RC outputs to inform operational and resource decision making.

And, third, continue to incorporate RCP into FDA business processes and operations, including

integrating into financial processes like budget planning and execution, hiring required talent to support and sustain the RCP capability, and establishing that long-term support model for the RCP capability. And I believe that is my last slide and I will -- I'll turn this over to Booz Allen Hamilton and Athena Tang and Kendra Orjada will speak to the findings from their study.

ATHENA TANG: Thank you, Josh. Good morning. Thank you all very much for your time. My name is Athena Tang, and with my Booz Allen Hamilton colleague, Kendra Orjada, we'll pleased to provide a walk-through of the evaluation (inaudible) capacity planning adjustment methodology. Next slide.

So, to begin, as part of the PDUFA 6 and the (inaudible) commitment, FDA contracted Booz Allen to conduct an independent evaluation of FDA's proposed capacity planning adjustment methodology. The resource capacity planning adjustment, which we'll refer to as the CPA, is an adjustment by FDA during the calculation of the target revenue to account for any additional resource needs because of an increase

in (inaudible) that exceeds current available funding. FDA developed new (inaudible) methodology that they are proposing to implement in lieu of the previous (inaudible). The scope of the evaluation was focused on examining this proposed CPA methodology and its ability to assess the sustained workload and resource needs for the PDUFA and BsUFA user fee program in comparison to the interim CPA methodology.

So, a review of the interim and proposed CPA methodology is on the following slide along with the findings and recommendations of the evaluation. I also want to note that Booz Allen is performing a similar valuation of application of the CPA methodology for the PDUFA program, which we'll talk about briefly in a few slides. Next slide, please.

So, currently, only PDUFA employs interim CPA methodology, as Josh mentioned previously in his slides. The interim CPA methodology is a four-step process that takes the workload volume and time reporting data and produces a CPA factor, which is its total workload adjustment percentage. So, very

quickly, the four steps include Step 1, calculating the historical workload volume with a three-year average; Step 2, calculating the percentage change between the three averages across two fiscal years; Step 3, apply a weighting average for each submission category and calculating a weighted percentage change; and, Step 4, summing all of the weighted averages. The CPA occurs once the inflation adjustment has been applied but prior to program-specific adjustments. Next slide.

As I mentioned earlier, Booz Allen is also valuating where the CPA methodology could be used by the PDUFA program. The key adjustments are to valuate if the FDA's proposed CPA methodology could be applied, and also determine if the proposed methodology could be used to monitor and report on resources.

In addition, Booz Allen is also providing recommendation to win considerations that could feasibly approve the proposed methodology as a result.

Overall, at this time, we believe the

evaluation findings and recommendations of the CPA align with the outcome of the PDUFA and BsUFA evaluation. And, in short, a similar approach can be applied for use by the (inaudible) program. However, there are some program-specific references that will be reflected in Booz Allen's findings and recommendations. And, again, more to come once the evaluation is complete. And similar to the PDUFA and BsUFA report, the GDUFA report will also be published. Next slide.

So, in general, to conduct the analysis of the proposed CPA methodology, Booz Allen used a bottoms-up hypothesis driven approach to ensure a structure and systematic analysis. The primary hypothesis was that the proposed CPA methodology represents improvement over the interim CPA methodology.

This was evaluated through the lens of whether the proposed CPA methodology addressed the four key issues of the interim CPA methodology identified by FDA. And also Booz Allen has about six evaluation criteria, which we'll walk you through, to

conduct a fair analysis of the proposed CPA methodology. And very quickly, these are accurate, defensible, meaningful, feasible, adaptable and efficient. Next slide.

So, in terms of the four key issues that FDA identified with the interim CPA methodology, the first one was that the interim CPA model is a lighting indicator. The interim CPA methodology just averages from the previous year's workload submission volume, which is a lighting indicator. Lighting indicators use insights into the past, however, they are not traditionally the best methods to use for future workloads. And as a result, the (inaudible) and the time it takes to hire and train new staff, program resources can be 3-4 years behind workload needs.

The second key issue was that the interim CPA methodology does not convert submission counts into resource demand. The interim CPA methodology produces a CPA factor in the form of a cost of percentage, and added the inflation adjusted base revenue (inaudible) assess the target revenue.

This does not accurately reflect the actual resource capacity and does not give any insight into how many FTEs are actually needed in order to meet workload demand.

The third key issue was that the interim CPA methodology does not account for complexity. And complexity in this context refers to the range of scientific and technical intricacies of human drugs. This can result in additional resource demand, (inaudible) regulatory issues and in special considerations, they require a review. The interim CPA methodology does not include a way to measure this complexity within the workload.

And, lastly, the fourth key issue was related to the commitment to support organizational review components engaged in direct review work. The interim CPA methodology does not account for the director review submission type of labeling supplement. And per the (inaudible) commitment letters, actually agree that the organizations within CPA that execute the direct review work (inaudible) volume receive the funds generated from CPA if current

funding does not cover cost. Next slide.

So, to conduct these valuations, Booze Allen developed hypotheses based on the six different criteria across the CPA (inaudible) which Josh covered in his steps. The driver assessment of the new methodology is potential effectiveness. This approach (inaudible) methodology against industry accepted quality, but it also provides continuity in evaluating the FDA's resource capacity planning method from previous workload adjusters' assessments.

The criteria we've selected we find to be realistic (inaudible) with the implementation of resource capacity client capabilities and in fairness with proposed CPA methodology. In the following slides we will cover how the proposed peak in methodology met each of the criteria defined here. Next slide, please.

Booz Allen created a data collection and aggregation process to perform the conceptual overall analysis of the proposed pre-pay methodology. Based on the analysis, we were then able to provide a recommendation to the FDA as they continue to

implement the methodology for the (inaudible) program. I've given the maturity of the methodology at the time of the evaluation, another analysis was done on the actual models. However, we were able to conduct a third review of the technical block indication on the approach that would be needed for the four-step process and annual support for the workload and resource financial casting models.

In addition, we held marketing sessions and interventions with FDA staff to discuss the forecasting models and use of the data. And now I'll turn the presentation over to Kendra, who will review the findings and recommendations of our evaluation.

KENDRA ORJADA: Thanks, Athena. So, based on the findings I'm going to cover in the next few slides, overall, there's evidence that the proposed CPA methodology is an improvement from previous methodologies employed. So, first, I'm going to cover the findings which align to the key issues and then I'll cover the evaluation criteria findings.

So, for the first key issue listed, the CPA methodology developed is forward looking and helps

to estimate the likely submission volume and the sustained resource demand required to support direct review workload. FDA built predictive models through advanced analytics techniques using multiple data sources which are leading indicators for submission volume.

The second key issue is addressed through the use of time reporting data to convert estimated submission volume into resource needs by FTE. Both historical time reporting data and submission volume will be analyzed to understand the level of effort, which helps convert the estimated submission forecast into an estimated resource demand.

So, for the third key issue, the proposed methodology will analyze the time -- or the historical time reporting data, which helps FDA capture a macro-level measure of complexity associated with the submissions. So, if the complexity of submissions is increasing, the time reporting data per application should also increase.

And for the final key issue, the proposed methodology includes all the direct review

submission categories, including labeling supplements, to assess the sustained workload and the resource needs of the user fee programs. So, previously, the interim methodology did not include this submission type. Next slide.

As for the evaluation criteria findings, Booz Allen was to -- was able to develop findings related to each criteria's definition that were shown earlier. So, for accurate -- the workload forecast models will likely represent the amount of submissions FDA received based on the approach used to predict submission volume. It captures major types of direct review workload, and to measure the resource needed to support sustained increases in workload.

So, as the methodology is implemented and as it matures, additional evaluations will be needed to test the accuracy of the forecast model by comparing the actual and predicted values.

For adaptable, the proposed methodology is capable of accounting for new and expanded data sources. This methodology utilizes Open Source software with R and Python, which can read a variety

of data formats. This software can also operate within different technology environments. In addition, the managerial adjustment process, which was Step 3 that Josh described earlier, can help FDA account for foreseeable business -- or, sorry -- for future business needs that would affect the resource demand.

In terms of defensible, we verified that the methodology aligns with the requirements that in FDARA and the PDUFA VI and PDUFA II commitment letters. FDA has developed a consensus around this proposed methodology through a series of working groups, which included individuals with workload and resourcing subject matter expertise.

In addition, the methodology and model development process are based on assumptions that FDA expects to remain true over time, and these assumptions are detailed in our report. Next slide.

So, for efficient, FDA plans to create a technical infrastructure that support automation and operationalization of the model development process, and Josh touched on this a little bit earlier. So,

this infrastructure will allow FDA to transition into a platform that considers efficiency, reasonability, scalability and stability as the primary drivers. Also, existing technologies will be used for forecasting, which are customized to meet the needs of the CPA process.

For feasible, the overall paradigm of the proposed methodology is fully documented and outlines the steps used to calculate the CPA factor for each user fee program. FDA was able to build the initial core set of workload and resource demand forecasting models using actual data. So, with this, there's evidence that FDA has the tools and data sources available to begin the implementation of the proposed methodology.

Lastly, for meaningful, the managerial adjustment process, which is the process to which decision makers within FDA will review the forecast and adjust FTE projected needs. So, this process is -- assesses the following factors: One, the accuracy of previous years' forecast, which help FDA understand how much to rely on the predictive models for

calculating any resource fees; whether the forecasts are sustained over the next three years, which allow FDA to assess if there will be a sustained workload, to justify the hiring of the new FTEs; hiring an attrition rates to help understand the realistic number of net FTE gains; and then, lastly, the availability of other sources of funding to help decision makers understand if there are other sources or other resources available to support the additional requisite FTEs.

And so these decision factors were verified to be interpretable by the decision makers and will likely give relevant business insights to help inform decisions on how to reasonably adjust the FTE count. Next slide.

So, through our assessment, Booz Allen identified these five recommendations that FDA should consider as the CPA is refined through continued implementation, which I'm going to cover in the next few slides. One thing to note is that these recommendations are to be considered long term. They are not intended nor required to be implemented in the

short term and should not prevent the methodology from being implemented as it's currently proposed. Next slide.

So, 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. Again, that's Step 3, which Josh described earlier.

A prediction interval is a range with an upper and lower limit, which the expected resource needs to lie. So, and that's based on a certain probability. So, using these prediction intervals, the decision-makers could assess the future uncertainty of the mean estimate produced by the resource demand forecast and make relative adjustments to the projected FTE needs.

This information would be incorporated -- or could be considered -- I'm sorry -- in whole with the other factors that I previously discussed in the managerial adjustment process, which may lead to enhanced accuracy of the adjustment. Next slide.

FDA may also consider whether increasing interpretability within the complex models used in advanced analytical techniques for workload forecasting would help inform the managerial adjustment process. So, model interpretability is a data find exercise that can help FDA understand why the models are estimating the specific number of submissions. This is done by providing insights as to how different variables from different data sources impact the forecast.

So, using this analysis, FDA may have an increased trust in the advanced analytic techniques that generate the forecast to help with accuracy. The outputs of a model interpretability exercise can be used in various what-if business scenarios for the decision-makers. So, if the model interpretability outputs and the what-if business scenarios may help provide additional meaningful output and, again, enhance accuracy of the adjustments. Next slide.

So, currently, FDA includes all the major submission types in the workload forecast models, but as the methodology continues to improve

yearly, FDA may want to perform data exploration to analyze how other more complex types of Directory B work, such as post-market safety and some subsets of policy and guidance development may be incorporated. So, data exploration will help to identify how to incorporate additional complex types of potential direct review work not currently captured in the forecast models. And by adapting the methodology to include other types of direct review work, this may allow FDA to more accurately calculate additional resource lead. Next slide.

So, again, as the methodology matures, FDA will continue refining the managerial adjustment process. And Booz Allen was able to identify information that may help FDA make further informed decisions during this process. First, FDA should consider evaluating the accuracy of the adjustments themselves made in previous years' managerial adjustment process.

So, 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 to improve its output. FDA should also consider developing business scenarios to include in the managerial adjustment process. So, rigorous decision framework should be implemented and validated as these business scenarios are built to ensure consistency and objectivity. The business scenarios will help the decision-makers understand current and future changes, and the user fee programs, the commitments and the priorities.

And, finally, FDA should consider generating hiring metrics regarding how long it takes to hire new FTEs. So, these metrics will help decision-makers understand the feasibility and timing of bring in the new FTEs on board. And, in whole, the recommendations may enhance the accuracy of the adjustments to the resource demand forecast. Next slide.

Okay, and the final recommendation. FDA should consider enhancing the documentation of the proposed CPA methodology to include overall methodology and assumptions and model decision-making rationale. So, first, as the methodology matures, FDA

should revise and enhance the assumptions for the overall process to reflect various iterations of the methodology. So, if the assumptions prove to be incorrect, this documentation can be used as a baseline to make necessary changes and to help with the continuous improvement of the methodology, which is a goal for FDA.

In addition, historical documentation -- or I'm sorry -- historical rationale should be documented to support FDA with future analysis that enhances efficiency by providing a baseline for the needed revisions. Since FDA will iterate on this methodology yearly, understanding the reasons behind the process and why decisions were made will allow FDA to leverage this information for future methodology revisions and, again, support continuous improvement, which is a goal. And to promote replicability and transparency, standard operating procedures should be created.

And, in all, all of this document will promote a more defensible methodology with clearly defined assumptions, rationale and procedures. And in

addition, it'll allow for more transparency and communication for stakeholders.

So, this concludes or overview for CPA methodology -- or, sorry, CPA evaluation. I appreciate your time. And now I'll turn it over to Jay Tyler to provide further FDA updates.

JAY TYLER: All right, thank you, Kendra. So, I'm going to provide an update on FDA's response to the financial evaluation that was conducted by the Health Federally-Funded Research and Development Center during FY 2018.

So, the Health FFRDC did a comprehensive evaluation of FDA's resource management, if you will, of our user fee programs. That evaluation focused on five areas and those five areas are displayed on the screen. I do want to emphasize that although the Health FFRDC did make several suggestions for improvements -- opportunities to enhance our overall resource management of our (inaudible) programs at FDA, they did not find any issues of noncompliance, that is, with Federal requirements in terms of federal financial management.

So, the evaluation focused on making sure FDA was implementing best practices. And so in response to that, FDA developed an action plan that, of course, includes strategic and tactical actions that FDA commits to taking. And I'm going to spend some time talking to you today about those action plans and our progress that we've made over the last year. I also want to remind folks that you can take a look at the action plan and our response on FDA.gov. Next slide.

So, overall, we're tracking well. We've made a lot of progress in fulfilling the actions laid out in the plan. We worked strategically to identify actions that will address the five focus areas in an integrated fashion. And, in fact, of the ten actions that are due to be implemented this year, we've already completed six of those actions, as indicated on your screen.

As a quick note, Focus Area 4, technical capabilities, are integrated across our actions for the other focus areas, which you will see through training and other issues the FDA targets,

increasing the knowledge base of FDA employees across the agency. And I want to reiterate that FDA is committed to continuous improvement, and we look forward to continuing to make strides toward the action plan. Next slide.

Most of FDA's efforts to improve the financial management of our (inaudible) programs focus on, again, expanding the knowledge base of FDA's employees and enabling FDA employees to keep pace with the increasing complexity by developing new resources and integrated training on existing tools, reports and systems.

So, we want to look close at a few of our assets that are depicted here, including the User Fee Manual, our integrated training effort, and the Fiscal Management Manual. FDA has developed a comprehensive manual for user fee financial planning and administration. Next slide, I'm sorry.

In February 2020, the first phase of this manual was internal coverage, which covered the general aspects of user fee financial management and aspects relating to the PDUFA program. The second

phase of the manual will be published for the FDA community by the end of this month and will focus on specifics related to the BsUFA and the GDUFA program.

In consolidating all of the agency's (inaudible) financial management refocused into one centralized location. The FDA is increasing the ease of access and agency wide awareness and understanding. We are on track to close this action by a scheduled due date, which is September of this fiscal year. Next slide.

With respect to our training efforts, we are in alignment with the focus areas. The FDA has taken an integrated approach to training, both developing new training courses, assimilating training on existing automated tools and reports, and incorporating these training requirements into the performance plans of applicable staff.

Specifically, we have developed and launched an instructor-led training on user fee financial planning and administration that launched in April of this fiscal year. We are also implementing an online version of the training that will be

available in September. We are in the process of working across the agency to develop and require training based on existing reports, automated tools, and automated tools and systems. We believe these integrated training efforts will further increase the technical understanding of FDA employees. Next slide.

In looking ahead for implementing the Fiscal Manual -- Fiscal Management Manual, I'm excited to introduce it. It will be a one-stop-shop for fiscal management resources, including all user fee financial planning and administration of resources. I think it will really help us support our agency and increase the knowledge of our employees. So, again, we're really excited about this new tool.

This is part of our effort to think innovatively about how we can continue to improve and better meet mission. So, with that, we'll now move into the public comment portion of the meeting and I'm going to turn it back over to Ms. Monica Ellerbe to give the instructions. Thank you.

MONICA ELLERBE: Thank you, Jay. In accordance with the Federal Registry (sound drops)

notice, we are now entering the open comments portion of the meeting where individuals will be able to have the opportunity to provide comments to the FDA. Please submit your comments using the following (sound drops) which is shown on the screen.

As previously mentioned, there is also a public docket open until July 21st, to which the public can submit comments. The comments will be captured on record and published in the meeting transcript. This concludes our meeting today and thank you so much to the presenters and the participations for joining us today.

As a reminder, meeting materials can be found on the FDA.gov webpage. Thank you very much and enjoy your day.

(Whereupon, at 10:11 a.m., the proceeding was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, IRENE GRAY, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

IRENE GRAY
Notary Public in and for the
STATE OF MARYLAND

CERTIFICATE OF TRANSCRIBER

I, SONYA LEDANSKI HYDE, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

SONYA LEDANSKI HYDE