

## 1 UNITED STATES FOOD &amp; DRUG ADMINISTRATION

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4 Public Meeting on Financial Transparency and

5 Efficiency of the Prescription Drug User Fee

6 Act, Biosimilar User Fee Act, and Generic

7 Drug User Fee Amendments

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## A P P E A R A N C E S

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3 Monica Ellerbe

4 Jay Tyler

5 Robert Marcarelli

6 Josh Barton

7 Athena Tang

8 Kendra Orjada

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## 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

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

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

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

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

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

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

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

22           ROBERT MARCARELLI: Thanks, Jay, and

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

6 In FY2019, FDA had net collections of  
7 1.015 billion in prescription drug user fees, spent  
8 1.017 billion for the human drug review process, and  
9 carried a cumulative balance of 220 million forward  
10 for future fiscal years.

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

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

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

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

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

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

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

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



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

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

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

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

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

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

4 In FY 2019, FDA had net collections of  
5 35 million in BsUFA fees, spent 42 million in user  
6 fees for the BsUFA program, and carried forward a  
7 cumulative balance of 32 million for future fiscal  
8 years. BsUFA II focuses on ensuring effective  
9 scientific coordination and review consistency through  
10 review, procedural and meeting performance  
11 enhancements.

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

22 FDA recently developed the Biosimilars

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

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

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

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

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

14 FDA's focus over the remainder of BsUFA  
15 II is to continue building enough staff capacity to  
16 develop on program performance and procedural goals,  
17 as outlined in the BsUFA II commitment letter.

18 Additional information is available in the FY 2019  
19 BsUFA Financial Report and the FY '20 Update to the  
20 BsUFA Five-Year Financial Plan. Next slide, please.

21 In FY 2019, FDA had net collections of  
22 497 million in human generic drug user fees, spent 465

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

3 (Audio Breaks Up)

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

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

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

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

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

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

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

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

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

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

1 enabling the fee setting with the capacity planning  
2 adjustment methodology.

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

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

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

22 So, real quick, what is resource

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

8 Building and maintaining the technical  
9 environment to support the RCP operationalization.

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

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

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

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

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

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

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

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

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

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

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

22 Overall, at this time, we believe the

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

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

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

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

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

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

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

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

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

1 funding does not cover cost. Next slide.

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 So, as the methodology matures, FDA may  
5 consider whether creating prediction intervals for the  
6 resource demand forecasts would add practical value  
7 for the decision-makers in the managerial adjustment  
8 process. Again, that's Step 3, which Josh described  
9 earlier.

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

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

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

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

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



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

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

20 So, if previous adjustments were too  
21 high or too low, FDA can evaluate the decisions made  
22 and identify the changes needed in the decision-making

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 Next slide.

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

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

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

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

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

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



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

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

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

16 (Whereupon, at 10:11 a.m., the  
17 proceeding was concluded.)  
18  
19  
20  
21  
22

## 1 CERTIFICATE OF NOTARY PUBLIC

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

17  
18 A handwritten signature in black ink, appearing to read 'IRENE GRAY', is written over a horizontal line. The signature is stylized with a large 'I' and a cursive 'G'.

19 IRENE GRAY

20 Notary Public in and for the

21 STATE OF MARYLAND  
22

## 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

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