UNITED STATES FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON FINANCIAL TRANSPARENCY AND EFFICIENCY OF THE PRESCRIPTION DRUG USER FEE ACT, BIOSIMILAR USER FEE ACT, AND GENERIC USER FEE AMENDMENTS

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C O N T E N T S

P R O C E E D I N G S

MONICA ELLERBE: Good afternoon everyone. I am Monica Ellerbe, and I serve as the Director of Business Management Services within FDA's Office of Finance, Budget and Acquisitions. And welcome to this year's Public Meeting on Financial Transparency and Efficiency of the Prescription Drug Use -- User Fee Act, Biosimilar User Fee Act, and the Generic Drug User Amendments.

At this time, FDA's Deputy Chief Financial Officer and the Director of the Office of Financial Management, Sahra Torres-Rivera will open and continue with the welcome and the overview.

Sahra?

SAHRA TORRES-RIVERA: Thank you, Monica. Good afternoon. We want to thank everyone for joining today's meeting. We appreciate your flexibility in joining us virtually and at the risk of your time.

As Monica mentioned, I am Sahra Torres-Rivera, and I am the Deputy Chief Financial Officer and the Director of the Office of Financial Management.

As part of the context for this meeting, the hour -- the hour-long meeting is part of FDA's commitment under PDUFA VI, BsUFA II, and GDUFA II, to enhance transparency and management of user fee

resources.

Previously public meeting covered the findings and FDA's response to the independent third-party evaluation of Program Research Management's duty in Fiscal Year 2018. This year, we are excited to provide an update on the significant amount of work that we have invested into furthering our ability to utilize program resources. Let's review the agenda.

Robert Marcarelli is the -- is the Director of the Division of the User Fees at the Office of Financial -- of Finance, Budget, Acquisitions and Planning, and will provide an update on the 5-Year Plan for PDUFA, BsUFA, and GDUFA.

Joshua Barton is the Director of Resource Capacity Planning at the Office of Program and Strategic Analysis, and will provide an update on the implementation of the Resources Capacity Planning capabilities and review improvements to the capacity planning adjustment methodology.

Lastly, I will provide an update on the progress we have made towards the FDA's action plans that was created in response to the Fiscal Year 2018 Financial Management Evaluation.

As communicated on the FR Notice, you will have the opportunity to provide public comment to

the FDA through the -- through the public docket. The public docket is open until July 19.

Without further ado, I would like to turn it -- turn it over to Robert to provide an update on the 5-Years' Plans.

Thank you.

ROBERT MARCARELLI: Thanks, Sahra. And good afternoon everyone. My name is Rob Marcarelli from FDA's Office of Finance, Budget, Acquisitions and Planning, and I will be providing an update on the Human Drug User Fee 5-Year Financial Plans.

Next slide, please.

In FY 20, FDA had net collections of $1.02 billion in prescription drug user fees, spent $1.076 billion in user fees for the human drug review process, and carried a cumulative balance of $194 million forward for future fiscal years.

Under PDUFA VI, FDA is implementing numerous commitments made under the user fee agreement, as well as new programs mandated by Congress in FDARA.

FDA is continuing to make significant progress implementing important PDUFA VI commitments, including enhancing patient safety and integrating it into regulatory decision making, enhancing regulatory science in use of real-world evidence, expediting drug

development, enhancing benefit/risk assessment in 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 through required electronic submissions and standardization of electronic drug application data.

Some additional commitments made in PDUFA IV include 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 for approved drugs.

FDA is also committed to the Regenerative Medicine Advanced Therapies Program designated by the 21st century CARES Act, which facilitates development of PDUFA regenerative medicine products. FDA looks forward to the remaining years of PDUFA VI being a period of strong innovation in drug development.

Recently, FDA embarked on an initiative to modernize the New Drugs Regulatory Program and will continue this modernization of the remainder of PDUFA

VI. These changes are intended to free 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 sure 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.

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

Under PDUFA VI and BsUFA II, FDA made commitments to establish a Resource Capacity Planning function and to modernize it's time reporting approach. CDER and CBER have now implemented Modernized Time Reporting and have established the foundational Resource Capacity Planning capability. This capability will continue to mature over the coming years as more data are collected and workload forecasts are continually refined. This will enable better forecasting of workload and the ability to translate forecasts into more targeted human resource and financial needs, helping to ensure FDA has the resources it needs to deliver on all its performance commitments.

With the foundational Resource Capacity Planning capability now in place, FDA has implemented the new capacity planning adjustment methodology. This methodology addresses the annual target revenue amount to account for the resources required to respond to

projected sustained changes in program workload.

Additional information is the FY 20 PDUFA Financial Report and the FY 21 Update to the PDUFA 5-Year Financial Plan.

Next slide, please.

In FY 20, FDA had net collections of $38 million in BsUFA fees, spent $34 million in user fees for the BsUFA Program, and carried forward a cumulative balance of $36 million for future fiscal years.

BsUFA II focuses on ensuring effective scientific coordination and review consistency through 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 facility 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 for these products.

During BsUFA II, FDA developed the Biosimilars Action Plan, or the BAP, which describes policies and actions to facilitate the efficient

development of review of bio -- biosimilar biological products. FDA continues to effectively allocate its fiscal and human resources to support priorities and adjust challenges and opportunities related to biosimilar biological products.

Most of the deliverables described in the BAP have been accomplished, including modernization of the Purple Book to a searchable online database that contains information about licensed biological products, including biosimilar and interchangeable biological products, the creation of the Office of Therapeutic Biologics and Biosimilars, and development and implementation of standardized biosimilar-specific review templates. A handful of deliverables remain in progress, including an evaluation of FDA's regulations regarding the submission and review of biologics license applications.

The BAP 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.

In the BsUFA II commitment letter, FDA committed to enhancing capacity for biosimilar regulations and guidance development, reviewer training, and timely communication, as well as strengthening staff

capacity to deliver information concerning the date of first licensure and the referenced product exclusivity expiry date to be included in the Purple Book.

As committed to the first three years of BsUFA II, FDA has enhanced capacity for addressing these important elements. This occurred through the growth of the Therapeutic Biologics and Biosimilar Staff, and its reorganization into the Office of Therapeutics, Biologics, and Biosimilars.

By increasing the number of staff dedicated to biosimilar activities during BsUFA II, FDA has been able to accomplish many significant desired milestones, including the finalization of almost all guidance documents specificied in the BsUFA II commitment letter, modernization of the Purple Book with an enhanced and user-friendly interface, and creation of an integrated multidisciplinary review template to enhance review consistency. Furthermore, FDA has expanded on education and outreach efforts during BsUFA II, creating new materials, webinars, and increasing attendance at outreach events.

As the number of biosimilar biological products available on the market increases, and more stakeholders have the opportunity to use biosimilar products, outreach and education will be fundamental to

facilitating an accurate understanding of these products and their acceptance and use among key stakeholders.

Looking forward through FY 22 and the end of BsUFA II, FDA will continue its focus on improving the efficiency of the biosimilar product development and approval process, maximizing scientific and regulatory clarity for the biosimilar product development community, developing effective communications to approve understanding of biosimilars among patients, clinicians, and payers, and supporting market competition by reducing damming of FDA requirements or other attempts to unfairly delay competition. Some activities may include regulatory science projects to support the efficient development and review of biosimilar biological product applications, increasing review support for certain types of biosimilar labeling supplements, enhancing capacity for regulation and guidance development, and continued expansion of outreach and education efforts.

Additional information is available in the FY 20 BsUFA Financial Report and the FY 21 update to the BsUFA 5-Year Financial Plan.

Next slide, please.

In FY 20, FDA had net collections of $483 million in human generic drug user fees, spent $541

million in user fees for the human generic drug review process, and carried a cumulative balance of $157 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 ultimate goal of increasing consumer access to safe, high-quality, and affordable generic drugs, GDUFA II focuses on two major objectives: one, reducing the number of review cycles to approval; and two, increasing the approvals of safe, high-quality, low-cost generic drugs.

The program now has different review goals for priority applications and more communications touch points with industry. GDUFA II establishes a well-organized process to review complex generic 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 an 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. Strengthening development in review of hard-to

genericides complex products. FDA will continue to implement the Pre-ANDA Program for complex products, which features product development, pre-submission, and mid-review cycle meetings to help clarify regulatory expectations early in product development and during application review. Continuing support in development of business processes to increase first-cycle approvals, and to reduce the time to approval by increasing communication and collaboration between FDA and industry.

FDA will continue the controlled correspondence process that allows generic drug developers to ask questions prior to an end of submission. FDA will continue midcycle 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, continuing 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 continues -- continues working to improve the efficiency of the generic drug development review and approval process. FDA pursues efforts to maximize scientific and regulatory clarity with respect

to complex drugs. FDA also continues to work to close loopholes that allow brand-name drug companies to game FDA rules in ways that delay the generic competition that Congress intended.

Under GDUFA II, FDA committed to advance scientific efforts to develop new human generic 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 produce-specific guidances and recommendations for regulatory submissions.

As part of the Pre-ANDA Program, FDA developed and published 258 new and revised product-specific guidances in FY 20. The produce-specific guidances have provided industry with both draft recommendations on the design of bioequivalent studies and scientific advice pertaining to FDFs and drug substances 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 peer-reviewed scientific literature,

presented, and discussed at major medical and scientific meetings, and contribute to FDA's general guidance development.

Since FY 13, FDA has awarded 172 research contracts and grants. 17 new external contracts and grants were awarded in FY 20 in addition to the 18 ongoing projects receiving funding. A complete list of FY 13 through FY 20 awards can be found at FDA's website.

FDA continues to strive to hire scientific and regulatory staff while also making targeted strategic investments to enhance productivity, support of regulatory science and policy efforts, and ensure the availability of safe and effective generic drug products. FDA will continue working to ensure the financial resources available to the GDUFA Program are being invested to support the long-term sustainability and productivity of the Review Program.

Additional information is available in the FY 20 GDUFA Financial Report and the FY 21 Update to the GDUFA 5-Year Financial Plan.

Next, my colleague Josh Barton will provide an update on Resource Capacity Planning implementation.

JOSHUA BARTON: Thanks Rob. And good

afternoon to everybody. Thanks for joining us this afternoon for our public meeting.

I'm the Director of our Resource Capacity Planning staff in (inaudible), and I'll give -- give the update on the current state of the Resource Planning Capacity capability.

So, next slide.

So, if you've attended one of our meetings previously or if you've seen our -- our published plan on the -- on the FDA website, the first couple slides may look familiar to you.

But just to recap for everybody, you know, our vision for the RCP Program has really been to develop a unified and trusted resource -- resource management capability to foster innovation and maximize our operational performance to deliver on the mission or the programs to -- to paraphrase a little bit. So, it's really about ensuring operational performance and delivering on our -- on our mission.

The next slide.

So, what is Resource Capacity Planning? This is kind of our high-level conceptual overview of the idea of Resource Capacity Planning and what we're trying to accomplish. And really, we're trying to put our programs in a position to be able to anticipate the

resources that are needed to help support the programs, and particularly the review work, so that we're in a position where -- whereby we can staff up to the resource levels we need when we need them.

And how we go about doing this, we have three major workstreams. The first is what we call the Modernized Time Reporting, and this is -- these are new capabilities that CDER and CBER have put in place for the PDUFA, and BsUFA, and GDUFA Programs, to have -- to collect much more data on how -- how the organization is spending its time. And this really provides us with a wealth of additional data to really understand, you know, better -- better measures of level of effort, really what's driving our resource needs, and how -- and where the organization is really investing its time.

Time Reporting, of course, is retrospective. It's collecting data on things that have already happened. And our Workload Forecasting Workstream is our workstream whereby we are using analytics based on internal data as well as some -- some sources of external data to really model what is happening in the relevant industries, and how -- how that activity is likely to translate into regulatory submissions of different types, or are with the programs held -- like I say, get us in a better position to staff

the -- the likely coming workload.

Those two workstreams are pulled together in what we call our Resource Forecasting Workstream, where we translate likely submission numbers into measures of FTEs, full-time equivalents. And, you know, there -- there's many other steps in the -- in the process, but it's kind of the high-level overview. And at the same time, we're also looking at other operational data, things like what -- what are happening in the -- in the HR realm, what's -- what's happening in the financial realm. It's really contextual factors that help inform resource needs and optimal resourcing.

How these resource forecasts can be utilized by the organization, we can use them to help understand how we can best prioritize our existing resources, they can be used for the revenue adjustment for both PDUFA and BsUFA, that's the Capacity Claim Adjustment, that new methodology that was first implemented for setting of Fiscal Year '21 fees, which I'll speak a little bit more about. It can help inform hiring plans as well as financial forecasting to understand where we're likely to land from a financial perspective each year.

Next slide.

Let's kind of double-click on the

resource forecast a little bit -- and dig in a little bit, a little bit more deeply on how those resource algorithms are developed. We take the forecasted workload, as -- as I discussed regarding different submission types, and then with our resource algorithms, what we're really doing there is, if you -- is looking at the historical time reporting data that's been collected as well as the historical submission volume, and looking at the different levels of the organization, across different job roles and different -- different suboffices across -- across the organization, and then pulling that together to inform the FTE needs or the -- the resource algorithms, and -- then pulling that altogether into a summarized resource forecast that pulls altogether.

But the real takeaway here is that that resource algorithm piece is built on historical actual data, plus time reporting, and the submission volume.

Next slide.

So, since our -- our last meeting about a year ago, we have a couple of -- of key achievements to highlight. And this is organized across our different -- or our three major workstreams.

So, first within Workload Forecasting, we've established our second generation of workload

models. So, now with the experience of having gone through the process of establishing the models for both PDUFA and BsUFA, the submission forecasting models, understanding how they operate, and -- and getting that experience, we do -- we then refine these models through a dedicated effort and -- and have been able to continue to improve the -- the performance of those models while also working to make the effort required to deliver those models more efficient. Around GDUFA, we've established a set of -- of submission models for use for internal -- internal purposes.

Around Modernized Time Reporting, we continue to support the accuracy and the compliance of the time reporting across the organization. You know, this is a -- you know, really critical to ensuring that our -- our forecasts, you know, represent the -- the actual experience if -- of our -- of our review staff. So, we're continuing to -- continuing to support the accuracy and compliance, understanding how it can continue to make the time reporting easier for folks, while also ensuring we're collecting the data that we need to support the RCP capability and the other uses of time reporting.

Understanding resource utilization. We developed a set of reports, dashboards, and we have an

increasing volume of -- of ad hoc reports that we have been able to help support -- have different levels of management across the organization help understand resource and related efforts for their -- their areas of responsibility. So, really seeing an uptick in the -- the utilization of these data which is nice to see.

Around our Resource Forecasting workstream, we continue to improve our -- our algorithm design as we continue to collect more time reporting data. These -- these algorithms will continue to refine, and we'll continue to get feedback across the organization on the performance of these algorithms. And this will be, you know, an ongoing effort year over year to continually improve the algorithms that we use in the RCP capability.

And then informing business processes, we're working to fully integrate the RCP outputs within the processes within the organization to help support resource management, budgetary decisions, and other operational decisions as appropriate. And that will really be a large area of growth over the next few years.

And then thematically across all three of these workstreams, we really had an -- a significant focus on enhancing automation as well as quality control

across all three of these workstreams. So, where feasible, we're working optimize our -- our data pipelines, our -- our code, and our work processes to make things as automatable as possible where appropriate, and -- and to make our efforts more efficient, and then also building in quality control procedures throughout the lifecycle of RCP, you know, to really ensure that we have -- where we're ingesting quality data so that the outputs are -- are quality outputs and the forecasts are quality forecasts.

Next slide.

This is another kind of visual, to sort of visualize the, kind of the RCP pipeline, where on the front-end we're ingesting data, including regulatory submissions, our time reporting data, a text-based data from PDF documents, APIs from other data sources that that data is then cleaned, standardized, prepped, QT'd.

It's run through our algorithm development process to understand the Resource Forecasting needs through our advanced analytics or to forecast regulatory submissions, integrate that data, derive the -- the adjustment for the -- for the user fees, for PDUFA and BsUFA, for that -- so, the fee-setting where appropriate, and deliver a -- deliver and visualize reports for, you know, different levels of --

of management across the organization.

Next slide.

Speaking to kind of the theme of automation, the way that these, kind of mechanically, the different inputs are pulled together to produce the Resource Capacity Planning outputs, are really through a program that we've been calling the Algorithm Engine. We are in a -- searching for a more -- more catchy name, but that's what we have today.

So, the RCP Algorithm Engine just helps us streamline the ingestion of the -- the resource forecasts, the workload forecasts, and to develop and help the capacity planning adjustment and the other RCP out -- outputs, and help to manage that process and automate that process to the extent practicable.

So, this program has a set of modules, including a ETL module, a forecast module, and a CPA module, and then quality -- quality control procedures are then integrated across all of those modules to help ensure, you know, the quality of the processes and the output of those -- those processes.

Next slide.

So, the next couple slides, I'll be speaking about -- a little bit about updates regarding the capacity planning adjustment. The capacity planning

adjustment is the name of the -- the mechanism whereby we can adjust the fee revenue amounts, the annual fee revenue amounts when fees are set for each fiscal year for PDUFA and BsUFA, per the -- the current statutory authorization.

Now, if you attended our meeting last year, we did speak about the -- the capacity planning adjustment methodology. By statute for PDUFA and BsUFA, there's a process laid out by which we could approach establishing a new capacity planning adjustment for PDUFA to replace the existing methodology, and to establish for BsUFA for the first time, a similar methodology.

That process in the statute included the requirement to have a third-party study to assess options and recommendations, and that was conducted and published last year. And in last year's public meeting, the contractor, Booz Allen Hamilton, spoke to their -- their findings.

So, we implemented the new capacity planning adjustment for Fiscal Year 21 fee setting for PDUFA and BsUFA. And where the -- kind of the -- the visual share pick-up, you know, refers to the calculations I just sort of spoken to a bit in previous slides run through that process to reduce the capacity

planning adjustment outputs, kind of the analytical output.

And then the -- the next two that's kind of laid out here are sort of the -- the steps outside of that analytical program. The first being, assessing the feasibility of acquiring the needed resources.

So, this is a new concept that was introduced with the -- the new capacity planning adjustment methodology, whereby we assess the -- that the outputs of the -- of the capacity planning adjustment, you know, whatever -- if -- if there's a forecasted FTE gap, we assess whether that forecast or that FTE gap, whether it's reasonable and realistic to adjust the total annual fee revenue amount to provide for those FTEs.

The intent here was to ensure that there's some -- some checks to, you know, if the capacity planning adjustment, for example, says we needed 500 FTEs and, you know, it's not likely to be a reasonable onboarding target within one year, we -- we'd have a mechanism to adjust that to a reasonable and realistic amount.

So, once those -- the output is adjusted to a reasonable and realistic FTE amount, those FTEs are then converted into dollars with the -- the FTE cost

model that we utilize.

There's some other -- other enhancements as well around processes and systems, including we've established a set of tracking and -- and guidelines to ensure that any funds that are added to the annual revenue amount or the capacity planning adjustment funds, that they are -- they are targeted to the organizational review components engaged in the increasing direct review work. And if that for some reason those funds are -- are not able to be executed in support of those -- those organizational review components, that will hold those funds and not spend those funds and they'll -- they'll be added to the -- the operating reserve at the end of the fiscal year, so that those assurance fees will only be executed as committed to in -- in the establishment of the capacity planning adjustment through the PDUFA VI and BsUFA II negotiations.

Next slide.

And this is just kind of a -- I don't know, really kind of a high-level summary of -- of some of the issues that were addressed with the new capacity planning adjustment methodology from the late fee methodology.

So, as noted earlier, the previous

adjustment only applied to PDUFA, not the BsUFA. So, the new adjustment applies to both PDUFA and BsUFA.

And the previous adjustment with -- previous adjustment methodology for PDUFA utilized a lagging indicator, so it used a set of three-year averages, and that was a bit -- a bit challenging when we were in a -- seeing long-term increases in workload and submission volumes. This is being retrospective and being a lagging indicator, would always -- a bit behind the curve, so to speak.

So, that's why the -- the new adjustment methodology uses this forward-looking approach, using validated forecasting models to help understand the directionality of work and -- over the next couple of years.

The late fee methodology also did not translate volume into expected resource demand, or, i.e., FTEs needed. So, the output was simply a percentage, which was a bit hard to try to interpret -- interpret and explain what exactly that was -- those percentages meant. The new methodology, it incorporates time reporting and submission data to translate into FTEs needed. So, it's a bit more interpretable and -- and is also built on actual historical time reporting, and -- and submission data as noted earlier.

Next slide.

All right. So, where are things going for RCP? Model and algorithm enhancements, this will be an ongoing activity where we will always be continually -- continuing to improve our -- our forecasts, our submission forecasts, our -- our resource algorithms as we collect more data, as we have more experience with the -- with the modeling of the -- of these phenomenon. And as -- as shifts occur within that -- the ecosystem, we'll continue to work and adapt to meet those needs.

Around operation support framework and business process and support model, we'll really be working a lot over the next few years to ensure we have a strong support model to sustain the Resource Capacity Planning capability, and then really build that further and integrate it further into the resource management and operation decision making processes across -- across the organization. So, we're fully utilizing the RCP capability.

And then the last item here, technical environment design and deployment, this is really focused on providing and industrializing the RCP capability through the appropriate IT and analytics environment. So, really ensuring we have the full, kind of, end to end analytics platform, IT platform, to fully

support and sustain and maximize the efficiency of this capability. And enabling -- our analysts really focus on improving the models and -- and expanding the -- the utility of the capacity funding capability internally, rather than having to process data manually.

So, I think, you know, there's a lot of -- - and exciting items here, I think, on the horizon here for RCP. I really see the last two years we focused on building the foundation and proving the concept, and we've -- we've now done so. And so now, it's really focusing on fully integrating these and sustaining and -- - and fully utilizing the RCP across the organization where appropriate.

So -- so -- yeah, it's been a -- been a interesting and fun couple of years, and -- and we'll have plenty of work for the next -- next couple of years as well.

And so, with that, I think my time is done. Go to the next slide. Thanks to everyone again for -- for joining us this afternoon. And I'll -- I'll turn this back to Sahra.

SAHRA TORRES-RIVERA: Thank you, Josh.

I'm excited to provide -- I'm sorry. Just -- yes. Thank you, Josh.

I'm excited to provide FDA progress on

the Action Plan that the Agency developed in response to the Fiscal Year 2018 Financial Management Evaluation. For those who were not able to attend the previous public meetings, we previously reported out on our findings of our independent third-party Financial Management Evaluation.

Evaluation was conducted by the Health FFRDC, a federally-funded research and development center that is sponsored by the Department of Health and Human Services. A comprehensive evaluation -- our comprehensive evaluation was attentive to five specific areas, which are shown and provided -- which are shown here in the slide, and we were provided recommendations on best practices to help ensure that FDA user fee financial management capability is consistent with the best practice in the federal government.

In response, the FDA developed an Action Plan that includes strategic and tactical actions that the FDA committed to take. I want to make sure that everybody's aware that the Action Plan can be found in the FDA website at fda.gov. We're going to go and I'm going to spend some time now discussing our progress.

As you can see here, we have five different focus areas, and here we can see the detail of all those actions. Overall, I have to say that the

Agency is tracking well and we have made great strides in fulfilling the actions laid out in the Plan.

In developing the Action Plan, we worked strategically to identify the actions that would address the specific areas in an integrated fashion. As you can see, we have completed most of our actions. Most of the more recently completed actions were in area 1, which I will provide more detail shortly.

We are still working on one action in the area number 2, which could respond to the administration of Fee Program resources, which we are on track to complete by the end of this September of this fiscal year.

I think that it is important to always keep in mind and perspective that FDA continues to be committed to improve and look forward to the improvement -- and we look forward to closing out our Action Plans.

Much of the FDA efforts to improve the financial management of User Fee Program is aimed at expanding the knowledge base of FDA employees. The approach moving forward enables FDA employees to keep up with the increasing complexity by the -- developing new resources and integrating training and resources on existing tools of reports and systems.

We are going to now take a closer look at

a few of our efforts and accomplishments that are illustrated here, including the Fiscal Management Manual, the User Fee Manual, our user fee training, and efforts -- efforts and IBAPS reporting training, and the DCFO major dashboard.

The Fiscal -- Fiscal Management Manual was launched in October of the last year. We call the Fiscal Management Manual our FFM, and it's an FDA-wide one-stop shop for all finance -- for all fiscal management resources, including all user fee, financial planning, and a new special resources (inaudible) in the User Fee Manual.

The FFM is part of our effort to think with innovation about how we can continue to improve and better meet our mission. The FFM has over 2,800 documents. The FFM helps us support the Agency and increase the knowledge of our employees. I think that is great to be able to share with you then since we launched the FFM last October, it has been visited over 56,000 times by FDA staff.

I would like to talk now, a little bit now about the User Fee Manual. The User Fee Manual, the UFM, was developed as part of FDA Action Plan specifically for area number 1. Resource Planning request an allocation and user fee administration. FDA

developed a comprehensive manual for user fees, financial planning administration. This manual has overarching knowledge and contribution from the programs, financial, and important areas.

The -- the deployment of the UFM covered three phases. Our first phase covered the general aspect of user fees, financial management, and efforts related to produce a program, and was launched last April, last year, on 2020. The phase two looked at specifics related to BsUFA and GDUFA Program, and it was launched in June last year. And finally, the phase three incorporated 13 user fee programs, including ADUFA, AGDUFA, CQA, and (inaudible), et cetera, and was launched in January this year.

As part of our organization, larger effort to identify areas for innovation, and maintain the (inaudible) in the User Fee Manual, FDA recently launched an automatic bot to scan for invalid reference links on the User Fee Manual, and generate a report on the scans. The go-live for this was last April -- I'm sorry, last February, and we used it for the first time in April.

The automated solution helped streamline the ongoing manual and time intensive process of validating over 150 links in this manual. Since --

since November 2020, the User Fee Manual was accessed over 700 times by over 150 unique users. At the time the UFM -- UFM was the most -- at that time, the UFM was the most accessed document on the FFM.

The User Fee Manual is currently being updated to include language for sections pertaining to the Over-the-Counter Monograph Program, OMUFA, incorporate updates based on the changes to the User Fee 5-Year Plans for the three user fees, BsUFA, GDUFA, and PDUFA. Updates to the User Fee Manual will be completed by the end of this month.

In consolidating all of the Agency's latest User Fee Financial Management Resources into one centralized location, the FDA is increasing ease of access and Agency-wide awareness and understanding of our User Fee Programs.

Next slide.

The user fee training, in alignment with all areas, the FDA has taken an integrated approach to training, developing new training courses, improving training on existed -- existent automated tools and reports, and incorporating these training requirements into the Performance Plan of the applicable FDA staff.

One of the prominent training is the user fee training, which educates FDA employees on the User

Fee Program, rules and responsibilities, process, important operations, and activities. In the past, FDA has conducted -- conducted 12 FDA user fee training sessions to 194 employees, advocating their understanding of billings, collections, and voluntary activity for their roles.

I think that is important to share that as we mentioned, we did incorporate these training requirements into the Performance Plan of the applicable FDA staff. The training has been such a success that we currently have people just taking it in order to further their understanding of the User Fee Programs.

We're going to pass now to the Action items -- or Action 3 for the area 2. In response to the Action 3 of the area 2 in the FDA Action Plan, FDA Center offices and staff have also undergone training on existing automated tools and reports.

FDA took the time and the -- put the effort to identify the use patterns of IBAPS and FBIS reports and paired them with the Center's collected data. This data was used to provide training to staff and help in understanding and enhance the usage of the reports available. FDA has also reviewed the Center's submissions of the IBAPS and FBIS Reports already being used, and how they're being utilized. We also analyzed

system-based and user report usage, and created an inventory of reports. These reports are living documents that are updated, and when the report is approved and available, then it's approved and available to the FDA community.

For Action item 3, the inventory report -- the inventory reports were shared and the training was completed with all Centers in Fiscal Year '20. Additionally, as part of every daily -- daily support for Fiscal Year '21, we have conducted 42 outreach (inaudible) sessions, with over 237 attendees, and 11 sessions are currently in progress.

Next slide.

In April of this year, we launched the Deputy Chief Financial Officer Metrics Dashboard to help FDA leadership make informed decisions to improve the fiscal health of the FDA. The power IV-based dashboard consolidates 34 reports and 8 systems to provide one-stop shop for Financial Management Metrics. The dashboard contains 36 metrics across the area of travel, user fees, accounting transactions, invoice and payment, reconciliation, and then 36 metric measurements.

Among the 36 metrics the dashboard, we have three that are user fees related metrics. We make accessible to everyone the user fees net collections by

programs, unearned revenue, balance, and aging of the user fees accounts receivables.

The user fees related metrics help provide FDA leadership with a system to track user fees collection, assess against acceptable targets for the year, and maintain a strong oversight of the User Fee Program. The dashboard also provides a centralized location for key OFM related metrics.

With that, I will pass it over to Monica for the meeting wrap up.

MONIC ELLERBE: Thank you, Sahra, and thank you to our other presenters, Rob Marcarelli, and Josh Barton.

In accordance with the Federal Registry Notice, we are now entering the open public comment portion of the meeting where individuals will have the opportunity to provide comments to the FDA.

As previously mentioned, there is a public docket opened until July the 19th, which will be open to the public and you can submit comments. The comments will be captured on record and published in the meeting transcripts.

This concludes our meeting, and thank you again for joining us. Please remember that you can find this information and the presentation on fda.gov. Thank

you.

(Whereupon, the foregoing was concluded.)

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I, TERRELL LEE, 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.

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Notary Public in and for the

STATE OF MARYLAND

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SONYA LEDANSKI HYDE

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Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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