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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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1 P R O C E E D I N G S

2 MONICA ELLERBE: Good afternoon everyone.

3 I am Monica Ellerbe, and I serve as the Director of
4 Business Management Services within FDA's Office of
5 Finance, Budget and Acquisitions. And welcome to this
6 year's Public Meeting on Financial Transparency and
7 Efficiency of the Prescription Drug Use -- User Fee Act,
8 Biosimilar User Fee Act, and the Generic Drug User
9 Amendments.

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

14 Sahra?

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

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

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

1 resources.

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

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

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

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

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

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

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

6 Thank you.

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

12 Next slide, please.

13 In FY 20, FDA had net collections of
14 \$1.02 billion in prescription drug user fees, spent
15 \$1.076 billion in user fees for the human drug review
16 process, and carried a cumulative balance of \$194
17 million forward for future fiscal years.

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

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

1 development, enhancing benefit/risk assessment in
2 regulatory decision making, enhancing regulatory
3 decision tools to support drug development, reviewing,
4 enhancing, and modernizing the FDA drug safety system,
5 and improving the efficiency of human drug review
6 through required electronic submissions and
7 standardization of electronic drug application data.

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

17 FDA is also committed to the Regenerative
18 Medicine Advanced Therapies Program designated by the
19 21st century CARES Act, which facilitates development of
20 PDUFA regenerative medicine products. FDA looks forward
21 to the remaining years of PDUFA VI being a period of
22 strong innovation in drug development.

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

1 VI. These changes are intended to free up resources so
2 that our scientists have more time to focus on drug
3 development, particularly for unmet medical needs and on
4 the multiple collaborations needed to make sure
5 candidate drugs are developed and assessed properly with
6 appropriate input from external scientists, expert
7 physicians, and patient communities. The initiative
8 includes regulatory and review process changes as well
9 as organizational restructuring.

10 FDA also intends to strengthen the
11 institutional support structures, including personnel
12 and information technology, that underpin the regulatory
13 process.

14 The initiative highlights the following
15 strategic objectives: recruiting the best and brightest
16 individuals to promote scientific leadership, enhancing
17 FDA's focus on interdisciplinary teams, prioritizing
18 operational excellence, and improving knowledge
19 management, emphasizing the importance of safety across
20 a drug's life-cycle, and incorporating the patient's
21 voice in regulatory decision making.

22 The changes to the PDUFA VI fee structure
23 are improving the predictability of FDA funding,
24 maximizing efficiency by simplifying the administration
25 of user fees, and enhancing the flexibility of financial

1 mechanisms to improve management of PDUFA Program
2 funding.

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

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

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

1 projected sustained changes in program workload.

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

5 Next slide, please.

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

10 BsUFA II focuses on ensuring effective
11 scientific coordination and review consistency through
12 procedural and meeting performance enhancements. FDA's
13 commitments also include enhancing capacity for guidance
14 development in specified areas and expanding review
15 staff capacity and training.

16 As part of BsUFA II, FDA will continue to
17 facilitate the development of biosimilar biological
18 products, including interchangeable biosimilars through
19 the strategic development of FDA's Biosimilar Biological
20 Product Review Program, and through an ongoing
21 clarification of the approval pathway for these
22 products.

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

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

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

18 The BAP aligns with FDA's strategic
19 priorities and reflects FDA's commitments in the BsUFA
20 II goals letter, innovations in regulatory science, and
21 expanded opportunities for collaboration.

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

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

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

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

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

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

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

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

23 Next slide, please.

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

1 million in user fees for the human generic drug review
2 process, and carried a cumulative balance of \$157
3 million forward for future fiscal years.

4 Under GDUFA II, FDA continues to
5 modernize the Generic Drug Program by improving the
6 program's efficiency, quality, and predictability. With
7 the ultimate goal of increasing consumer access to safe,
8 high-quality, and affordable generic drugs, GDUFA II
9 focuses on two major objectives: one, reducing the
10 number of review cycles to approval; and two, increasing
11 the approvals of safe, high-quality, low-cost generic
12 drugs.

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

23 FDA will continue to expand upon
24 improvements made in the following areas in GDUFA II.
25 Strengthening development in review of hard-to

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

11 FDA will continue the controlled
12 correspondence process that allows generic drug
13 developers to ask questions prior to an end of
14 submission. FDA will continue midcycle communications
15 during the review of an original ANDA when further
16 information or clarification is needed, or would be
17 helpful to allow completion of FDA's review, continuing
18 implementation of FDA's Drug Competition Action Plan,
19 which focuses on developing and implementing general
20 policies to further expedite the availability of generic
21 drugs.

22 FDA continues -- continues working to
23 improve the efficiency of the generic drug development
24 review and approval process. FDA pursues efforts to
25 maximize scientific and regulatory clarity with respect

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

5 Under GDUFA II, FDA committed to advance
6 scientific efforts to develop new human generic products
7 and novel dosage forms. Through its regulatory science
8 initiatives, FDA continues to work on developing tools,
9 standards, and approaches to assess these products and
10 facilitate the path to market approval. One example of
11 FDA's commitment to this program has been its produce-
12 specific guidances and recommendations for regulatory
13 submissions.

14 As part of the Pre-ANDA Program, FDA
15 developed and published 258 new and revised product-
16 specific guidances in FY 20. The produce-specific
17 guidances have provided industry with both draft
18 recommendations on the design of bioequivalent studies
19 and scientific advice pertaining to FDFs and drug
20 substances that can be used in the development of
21 generic, complex, and noncomplex drugs.

22 In addition to serving as the scientific
23 basis for the development of product-specific guidances
24 and specific Pre-ANDA communications, research outcomes
25 are published in peer-reviewed scientific literature,

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

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

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

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

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

25 JOSHUA BARTON: Thanks Rob. And good

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

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

7 So, next slide.

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

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

20 The next slide.

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

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

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

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

1 the -- the likely coming workload.

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

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

24 Next slide.

25 Let's kind of double-click on the

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

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

19 Next slide.

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

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

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

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

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

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

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

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

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

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

11 Next slide.

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

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

1 of management across the organization.

2 Next slide.

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

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

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

22 Next slide.

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

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

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

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

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

1 planning adjustment outputs, kind of the analytical
2 output.

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

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

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

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

1 model that we utilize.

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

19 Next slide.

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

25 So, as noted earlier, the previous

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

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

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

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

1 Next slide.

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

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

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

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

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

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

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

22 SAHRA TORRES-RIVERA: Thank you, Josh.

23 I'm excited to provide -- I'm sorry.

24 Just -- yes. Thank you, Josh.

25 I'm excited to provide FDA progress on

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

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

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

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

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

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

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

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

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

25 We are going to now take a closer look at

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

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

13 The FFM is part of our effort to think
14 with innovation about how we can continue to improve and
15 better meet our mission. The FFM has over 2,800
16 documents. The FFM helps us support the Agency and
17 increase the knowledge of our employees. I think that
18 is great to be able to share with you then since we
19 launched the FFM last October, it has been visited over
20 56,000 times by FDA staff.

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

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

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

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

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

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

5 The User Fee Manual is currently being
6 updated to include language for sections pertaining to
7 the Over-the-Counter Monograph Program, OMUFA,
8 incorporate updates based on the changes to the User Fee
9 5-Year Plans for the three user fees, BSUFA, GDUFA, and
10 PDUFA. Updates to the User Fee Manual will be completed
11 by the end of this month.

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

17 Next slide.

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

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

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

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

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

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

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

6 For Action item 3, the inventory report -
7 - the inventory reports were shared and the training was
8 completed with all Centers in Fiscal Year '20.

9 Additionally, as part of every daily -- daily support
10 for Fiscal Year '21, we have conducted 42 outreach
11 (inaudible) sessions, with over 237 attendees, and 11
12 sessions are currently in progress.

13 Next slide.

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

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

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

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

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

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

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

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

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

1 you.

2 (Whereupon, the foregoing was concluded.)

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, TERRELL LEE, the officer before whom the
3 foregoing proceedings were taken, do hereby certify that
4 any witness(es) in the foregoing proceedings, prior to
5 testifying, were duly sworn; that the proceedings were
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SONYA LEDANSKI HYDE

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Federal Rules of Civil Procedure

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.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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