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Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments
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>> KICHELLE JOSEPH: Good morning, we're going to allow a few minutes for additional people to join the session. We'll get started soon.

Good morning. I'm Kichelle Joseph, the acting director of the Office of business services. Welcome to this year's public meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments. Thank you for joining us today for this meeting. We appreciate your attendance. This meeting is being recorded and will be available following the meeting. To begin today's session, I would like to introduce FDA's Chief Financial Officer, Benjamin Moncarz.

>> BENJAMIN MONCARZ: Good morning. Thank you. I'm the Chief Financial Officer of FDA's Office of Finance, Budget, Acquisitions, and Planning.

I'm excited to be here today with you for this annual session. This meeting is part of FDA's commitment under PDUFA VII, GDUFA III and BsUFA III to enhance transparency of the financial management of the user fee resources, these programs were reauthorized as part of the user fee authorization act in 2022. This year we're really excited to provide an update on the significant amount of work that the agency has invested to further strengthen our ability to utilize program resources. As we begin, I'd like to go over our agenda.

Today a few of my colleagues within the FDA will be here to discuss topics related to the transparency and efficiency of GDUFA, PDUFA, and BsUFA. You just heard from Kichelle Joseph. Coming up you will hear from Olufunmilayo Ariyo, the director of the user fee support staff within the Office of financial management in FDA's Office of finance, budget, acquisitions and planning. Olufunmilayo Ariyo will provide an update on the five-year financial plans. After that update, we will turn it to Josh Barton. Director of the resource capacity planning staff within CDER. He will discuss fee setting process

and then we will turn it over to Bethany Rue, a data scientist at the Office of Program and Strategic Analysis.

As you heard from Kichelle to open up us, Kichelle will conclude this session and provide you with important additional information.

As communicated on the Federal Register notice, you will have the opportunity to provide public comments to the FDA following this meeting. Your comments will be documented as part of the public record. The public docket is open until June 6, 11:59 p.m. eastern time. I'll turn it over to Olufunmilayo Ariyo to provide an update of the five-year financial plan. Thank you.

>> OLUFUNMILAYO ARIYO: Thank you and good morning, everyone.

My name is Olufunmilayo Ariyo with the FDA's Office of finance, budget, acquisitions and planning and I'll be providing the update on the five-year financial plans for the human drug programs. For each of the user fee programs we have provided actuals to the fiscal year 2023 total budgetary resources, obligations and carryover. We have included the plan estimates for the remaining fiscal years within the current authorization period from 2024 to 2027. These plan estimates undergo annual review and reassessment each fiscal year as the amounts from the previous fiscal year become available. These provide the baseline for future changes. Updates to the plan estimates occur on annual basis. FDA spends GDUFA, BsUFA, PDUFA collections and non-user fee appropriations to hire, support, maintain personnel for the review of the human drug product submissions. Today we're discussing the prescription drug user fee act, PDUFA VII. Two types of fees, application and program fees. The proportion of target revenue derived from the program fees remains at 80 percent and application fees remains at 20 percent. Net collections will equal the target amount. The PDUFA net collections estimate for fiscal year 2024 has been increased above the target revenue amount by an estimated $30 million because of the rate of collections this far this current fiscal year. The net collections estimate may be readjusted for the remainder of the fiscal year. PDUFA fiscal year 2024 estimated collections are $1.45 billion with future year recoveries estimated at $12.6 million. Total carryover represents the balance of unspent PDUFA fee funds. Funds considered available and unavailable. The total year carryover at the end of one fiscal year equals the total carryover at the beginning of the subsequent fiscal year. PDUFA fiscal year 2024 carryover is $275.5 million. Brings the total budgetary resources for PDUFA to $1.74 billion. The second table shows the actual and previously expand expenditures for 2023 and planned expenditures for 2024 through 2027 of PDUFA fee funds broken out into major expense categories which include payroll and operating, rent, and shared services cost.

PDUFA fees may be expended only for costs to support the process for the review of human drug applications as defined in PDUFA VII. The estimated total obligations for fiscal year 2024 funded by PDUFA fee funds amount to $1.4 billion. Due to the amendment in the FDC act, there is a reduction in the total cost associated with user fee spending. Now only costs for leasing and necessary scientific equipment related to the review of human drug applications will be included. As a result, expenses for facilities, fixtures, furniture and supplies will no longer be eligible for funding through PDUFA user fees. The PDUFA carryover table includes the estimated amounts for fees collected and not obligated at the end of the fiscal year. Fee collections from previous

years are currently unavailable for obligation. FDA sets aside 25 million for refunds in fiscal year 2024. Estimated fiscal year 2024 carryover net of unavailable and set aside funds comes to $248 million. Next slide.

Turning to the reauthorization of BsUFA III. It covers the actual and previously planned expenditures for fiscal year 2023 and planned expenditures for fiscal year 2024 through 2027. The first table connects the target revenue to net collections while showing the estimated budgetary resources for each fiscal year. We have total estimated BsUFA resources of $72.6 million. Estimated collections of about $58 million with estimated carryover net of the set aside funds of $13.4 million. BsUFA had a similar reduction in total rent from fiscal year 2023 to 2024 and after due to the amendment of the FDC act regarding the types of allowable costs for leasing and rental services.

Lastly, an adjustment to the fee amounts was not made in fiscal year 2023 or fiscal year 2024.

It's important to note that BsUFA application submissions have been high over the past two years. Leading to significant collections and increased workload. This trend may affect planning adjustment amounts.

Next is the third reauthorization of the GDUFA III. We have estimated total budgetary resources for fiscal year 2024 of $743.7 million which includes estimated collections of $613.5 million, estimated annual recovery of $10 million and unspent funds of $120 million which includes estimated carryover of $110 million. GDUFA estimated obligations also include the reduction in total rent for fiscal year 2023 to 2024 and after due to the amendment of the FDC act. Lastly for GDUFA, beginning with fiscal year 2024, FDA implemented the capacity planning adjustment to adjust as needed the fee revenue and fees to reflect changes of FDA for human generic drug activities, for 2024 the planning adjustment was $8.4 million. Thank you for your time. Next my colleague, Bethany, will present on resource capacity planning implementation.

>> JOSH BARTON: We're going to start with the PDUFA fee setting process and drivers of the application fee. Bethany will follow-up with the next section. Thanks, Funmi. I'm the Director of the Resource Capacity Planning Staff in CDER and I appreciate everyone joining, taking time out of your day and joining us for this meeting.

Interested parties have raised questions and concerned regarding the 25 percent increase in the PDUFA application fee that occurred in fiscal year 2024. This presentation walks through the PDUFA fee setting process that was agreed to by the FDA and industry and which is prescribed in statute. We want to talk through the drivers of the fee increase, the dynamics that impact that.

Before jumping into that process, a couple of basics to be aware of.

Fees in the PDUFA program are assessed to certain applications and certain approved products to collect the full PDUFA target revenue each year.

PDUFA is not a fee for service program. The collected fees pay for all of the allowable activities defined in statute. The application fees do not pay for the review of specific applications. All of the funds are pooled and are used to support all of the allowable activities that PDUFA fees can be used to support.

Next slide.

First, I'll talk through the PDUFA revenue setting process and then how that impacts the application fee amount.

This is the overall process. I'm going to step through each of the components but to give you a lay of the land, this is the process that we'll talk through. I'm going to go through this relatively quickly but the slides will be made available and this is a reflection of what is found in the fee setting Federal Register notices each year.

The first component is the base revenue amount.

This is not discretionary. The FY 23 amount, the first year of PDUFA VII, that amount is written into statute specifically and then in subsequent years, fiscal year 24 through 27 the base revenue amount is the prior year's total revenue amount minus adjustment for operating reserve and additional direct cost. Essentially, the base revenue amount plus inflation, hiring retention, capacity planning and additional dollar amounts becomes the next year's dollar amount, you can see the 24 and 25 amounts here. The FY 25 fee setting Federal Register notice has not been published yet because we know the base revenue amount.

Next slide.

The inflation adjustment is the next step. This amount is not discretionary. The statute lays out the process for applying the inflation adjustment each year.

There are two components to the inflation adjustment. One is the change in the average personnel and cost benefits per FDA FTE. Essentially, the total payroll costs plus benefits averaged across all FDA FTE. Not CDER or CBER specific FTEs. This is not a measure of PDUFA specific FTE but all 18,000 FDA FTEs. Another component is the local CPI in the Washington, D.C. area. Those are used in a weighted fashion based on the total proportion of PC and B to total cost in the program.

I know that's a lot but it's all laid out here and in the Federal Register notice. The strategic hiring, retention adjustment is not discretionary. The amounts are written into statute to support strategic hiring and retention needs. This was 9 million in fiscal year 23 and is four 4 in each subsequent year of the current authorization period.

The next step is capacity planning adjustment. This was established per a process that FDA and industry agreed upon in PDUFA six as a modernization of the long standing PDUFA workload adjuster.

There's some degree of discretion within the capacity planning adjustment that discretion is enabled through the managerial adjust process which was implemented with the new CPA in fiscal year 21. Prior to this time, the interim CPA and workload adjuster resulted in a full adjustment regardless of other factors. If the CPA or adjuster produced a number, that was used in fee setting. With the new capacity planning adjustment, this enables a potential downward adjustment of the CPA calculated FTE delta based on additional factors, including forecast performance, whether forecasts are expected to be sustained, ability to hire in a timely manner and whether other sources of funds are available to support the needed FTEs. The managerial adjustment has only results in the lowered adjustment. CDER had a forecasted CPA delta that was adjusted down because of the additional hiring that already had to happen in the program. This is a mechanism to make sure that any actual fee adjustment is realistic and reasonable to be used as needed to provide for the needed FTEs for the parts of the organization experiencing increases in the direct review workload.

The next step is the additional dollar amounts. These amounts are not discretionary. These are written in statute. Pursuant to FDA and industry's agreement to support new personal for negotiated enhancements -- to support FTEs for the new

enhancements in PDUFA VII. Next step is the operating reserve adjustment. The bounds are not discretionary. The maximum operating reserve amount is equal to the equivalent of 14 weeks of operations each year.

And the minimum operating reserve amount phases up from fiscal year 23 to 25 from 8 to 9 and then ten weeks moving forward.

The operating reserve does not include the approximately 79 million considered not available for obligation and if there's an adjustment, that does not impact future year's base revenue amounts. It's a onetime adjustment used to balance the operating reserves as needed.

The final step is the additional direct costs, these are written into statute. These amounts provide for operating costs that are associated with the agreed upon PDUFA VII enhancements. Program enhancements that require non payroll and operating costs. These funds are not included in the base revenue amount for subsequent years. These are specific amounts for specific years.

Through that process, those steps, the annual revenue amount for PDUFA is established. That creates the total revenue amount that the program is attempting to collect for the year. We don't actually collect it until the fees are invoiced and paid. That annual revenue amount is then divided up 20 percent to the application fees and 80 percent to the program fees. That 20/80 split is written into statute.

There's no flexibility with those allocation percentages. On the application fee side we take the annual revenue amount, 20 percent of that allocated to the total application fees, and that 20 percent is divided by an estimated number of fee-paying full application equivalents or FAEs for the year. We estimate the number of fees that will be paid and divide that 20 percent of the total revenue target to create that fee amount.

The FAE, full application equivalent. The definition is below. An application that requires covered clinical data counts as one FAE. An application not requiring covered clinical data counts as one-half and an application withdrawn before filing or refused filing counts as a fraction of an FAE. Similar process for the program fee. 80 percent of the annual revenue amount, divided by the estimated number of fee-paying programs expected to be paid for that year.

Next slide.

This table provides the actual amounts for the FY 23 and 24 fee setting. The top table walks through each of the components that I spoke to and shows the actual amounts for FY 23 and 24 and how they sum to the total annual target revenue amount.

It also shows the percentage increase from each component above that year's annual base revenue amount as well as the average increase across the two years. The process I spoke to about setting the application fees is shown in the lower table.

If we look at FY 23 and the total rounded, $1.3 billion. 20 percent of that establishes the application fee total, approximately $262 million. And in FY 23 the estimated FAEs was about 81. That $262 million divided by 81 sets the approximately $3.2 million fee amount. You can see the total annual revenue amount, 20 percent of that is proximately $284 million for the application fee total and the estimated fee paying FAEs was about 70. That sets the $4 million fee amount for the application fee for FY 24.

One thing to note, the negotiated enhancements are the largest contributor to the increase and total annual revenue amounts. The additional dollar amounts are for FTEs, for payroll for PDUFA VII enhancements agreed upon by the FDA and industry as well

as the direct costs, these are the largest contributors to the increase in the total annual revenue amount for both years here.

However, the change in the estimated fee-paying FAE is the most significant factor driving the fee increase in FY 24. The reduction in the estimated fee paying FAEs increased the fee by $530,000 by itself. To demonstrate the impact of the FAE change, the estimated fee-paying FAE number from FY 23 is used here. We take the 81 estimated fee paying FAEs from 23. If that were held constant into FY 24, the application fee would have been %3.5 million rather than $4 million. That change in the estimated FAEs in and of itself contributed to the $530K increase, 15 percent increase.

Next slide. A natural question is if the estimated number of fee-paying FAEs are going down, does that mean the workload of the program is going down?

That is the opposite of what we've been seeing.

This slide here, the top portion of the table are figures from the PDUFA performance reports, which show the number of original marketing applications submitted each year. This is broken up the way it's presented in the performance reports by original priority NME and BLA and then standards and priority standard for non-NME and BLA. The sources for these data are the FY 23 and 24 performance reports for PDUFA V and VI. The sum of the totals above are the total number of original NDAs and BLAs of marketing applications, then we have the fee paying FAEs from the fee setting Federal Register notices and then the proportion of fee paying FAEs to total NDAs and BLA. Then with PDUFA V and VI we show each year and the right most column has the annual average for each of the rows.

What you can see here is that the application review workload on average is increased in PDUFA VI over PDUFA V. The total applications increased from about 142 to 156 per year from PDUFA V to PDUFA VI. Overall, generally speaking more application review workload per year.

Currently, the proportion of NMEs, new molecular entities increased, driving more workload. These are more complex reviews, novel products. Take a fair amount of additional effort to complete the reviews. We're seeing that driving more workload and the annual average number of the NMEs or BLAs increased from about 52 in PDUFA V to almost 78. More total workload and the proportion of more complex reviews are also increasing.

Currently, fewer applications pay fees during that time. Fewer average annual fee paying FAEs from PDUFA five to PDUFA VI.

From about 77 per year in PDUFA V to closer to 73 per year in PDUFA VI and the percentage of fee paying FAEs decreased from 54 percent to 46 percent. While there's more workload and the fees are increasing, the number of sponsors paying the fee is decreasing concurrently.

Next slide. One thing to note. One dynamic we've seen in recent years is coming out of the COVID pandemic there has been what appears to be an increase in volatility around submission activity and the last three years as shown in the red box were the numbers estimated of fee paying FAEs. You can see those shifting from year to year.

We focused on the PDUFA application fee but similar dynamics can apply to the PDUFA program fees as well as GDUFA. BsUFA has avoided this partly due to design and partly due to industry growth. Where there's a fixed percentage allocation of the target revenue to specific fee types, fees will likely go up if the denominator estimator is

going down and fees will likely go down if the denominator estimator is going up. This may result in disconnects where fee amounts could shift independently from the overall workload of the program. BsUFA has been able to avoid this. It has a foreclosing percentage allocation of the target revenue. You can shift from year to year the percentages and use that to help balance the fee amounts.

For BsUFA, from fiscal year 18 to fiscal year 23, the application and product fees did not change while the BP D fees decreased. That floating percentage allocation helps with that. But BsUFA was also helped as the program workload has generally been increasing. There have been increases in the submissions related to the denominators associated with each fee type. This has helped to the management of the fees for BsUFA.

In summary, for PDUFA the application fees do not pay for the review of specific applications, they contribute to the funding of the totality of the PDUFA program. While workload has been increasing, fewer full application equivalents have been paying the fee. While the fee went up, the number of sponsors actually paying the application fees is going down. That means those paying must may a larger fee.

To mitigate this impact in the future, PDUFA may need more flexibility in fee setting. Fewer fee paying FAEs does not mean less work. It means more applications are getting waivers and workload has been increasing due to more total submissions and more complex submissions, similar dynamics to apply to other programs under similar conditions. I hope this provides insight into what is impacting the application fee amounts in PDUFA and some of the dynamics that may sometimes occur elsewhere and appreciate everyone's time and attention and I will turn this to Bethany Rue who will provide updates on the resource capacity planning implementation.

>> BETHANY RUE: Thanks, Josh. Good morning. I'm a data scientist on the resource capacity planning staff. Today I'll be providing updates on resource capacity planning implement information. PDUFA VII, BsUFA III and GDUFA III include a set of commitments which continue to build on financial enhancements to ensure optimal use of user fee resources and alignment of staff through the continued development of the agency's RCP capability. The implementation of the commitments specify that the agency will publish an implementation plan on how RCP will be leveraged and utilized. The resource capacity planning and modernized time reporting implementation plan was published per the commitments in March 2023.

Additionally, the agency provides annual updates on progress made towards the implementation plan. The first of these annual updates was published in March 2024. The following slides will summarize the updates provided in the first update to the RCP implementation plan. The 2024 implementation plan update provides information on the following topics. A feasibility assessment, the updated RCP concept of operations, the continual improvement of time reporting, the continual improvement of the CPA, integrating RCP analyses into financial and operational decision-making processes and the implementation of the GDUFA CPA.

I'll provide updates on each of these areas in the following slides.

RCP came out of the previous authorization period during fiscal years 2018 to 2022. In March 2018 the first RCP implementation plan was published. This included five phases of implementation. The first three continually undergo improvement. These are the resource management foundation accelerator, support model and organization

design and resource management and deployment and closed planning. FDA has engaged a contractor to conduct a feasibility assessment of phases four and five of the RCP plan. Phase four specifies integrating project management with process planning and five specifies portfolio analytics and reporting. This is expected to be completed by the end of the calendar year 2024.

Building on the RCP planning of the previous authorization period, FDA is focused on staining, refining, and expanding the RCP capability. FDA is currently engaged in an effort to refine the existing RCP support and operating model. Concurrently, refinements of the operating model for the ITR program are being explored as it continues to be implemented through the agency. The insight system oversight board has been established to coordinate ITR related activities across the agency.

I'll provide updates on time reporting across CBER, CDER, and ORA. CBER successfully transitioned its full-time reporting capability to ITR in September 2023. This provides new features to support CBER's continuing effort takes to improve time reporting. CDER institutionalized an annual review process under its ITR change control board.

In April 2023, ORA celebrating the one-year anniversary of the full implementation of ITR to all offices. ORA has pursued several initiatives to improve compliance and expand data accessibility. As the program reaches maturity, ORA will continue to use a data driven approach to make improvement to the code, guidance and procedures to ensure ORA fully realizes the potential of ITR.

We have continued to make enhancements and continual improvements to the CPA in technical, process, and statutory areas.

For technical enhancements we've established a cloud-based technology platform to support RCP in CDER and CBER. CBER and CBER are leveraging this environment. We've engaged in technical improvements to the code and forecasting models. These improvements have focused on streamlining the code based to increase efficiencies and fine tuning. We continue the annual variance analysis. For statutory areas, PDUFA VII expands the definition of the PDUFA program to include allergenics products, these were incorporated into the CPA model. Annual reports, post marketing requirements and commitments or PMRPMC active risk evaluation or REM were incorporated into the CPA as relevant for fiscal year 2024 fee setting.

RCP work products are will integrated into financial processes across the agency and work that's continued to adapt approaches to support offices in CDER and CBER. RCP is working to establish fit for purpose models to meet the needs of its offices. Model development efforts for internal uses are underway alongside an organizational needs assessment to help target opportunities moving forward.

These efforts will help bridge internal analysis needs. The future state of RCP is currently being assessed via the feasibility assessment I discussed earlier in the presentation.

Next slide.

The GDUFA CPA was implemented for CDER. CDER is focused on continual improvement. We're examining feasibility of forecasts prior approval supplements separately from changes being effects supplements. These would not be implemented before the fiscal year 2026 fee setting. We're engaging in standard continual improvement process including the annual variance analysis and identification of any

opportunities for continued enhancements. ORA is aiming for implementation of its portion of the GDUFA CPA fee setting.

>> KICHELLE JOSEPH: Thank you Bethany and thank you to all of you for attending, this concludes our meeting. I appreciate your time and attention. To close out the meeting, I have a few final pieces of information to share with you all.

Please forgive me, I'm trying to make sure I have it all up for you. To submit public comment, you will go to regulations.gov, use the docket number listed there to locate the meeting and submit your comments. You will have until July 6th at 11:59 p.m. eastern standard time to submit your comments. To access the materials from this meeting please visit the FDA.gov webpage listed below.

Thank you very much and have a good day.

[Recording stopped]