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

September 30, 2025, 1:29PM

0:12

Welcome to this year 's public meeting on financial transparency.
And efficiency of prescription drug user fee pdufa.
And efficiency of of prescription drug user fee pdufa biosimilar user fee act the sufa in generic drug user fee amendments gudufa.
Biosimilar user fee act the sofa in generic drug user fee amendments gudufa thank you for joining us today and we appreciate your attendance.
As a reminder we will not be taking any live questions within this public meeting.
You can submit your comments to the public docket.
So 1159 Eastern Time on October the 30th 2025.
You can find the public docket when the FDA meetings webpage or directly through the Federal Register.
We will display additional details at the conclusion of this meeting regarding accessing the public docket a few housekeeping items before we begin for those who are attending this meeting in person restroom facilities are located down the hall to the right of the conference room.
This event is being recorded and live streamed on the FDA YouTube channel as well as a transcription of today's meeting will be available with the slides and published on the FDA website.
Like following the meeting.
Today's agenda is displayed on the slide.
Coming up soon you will hear from Benjamin mark cars chief financial officer of the FDA.
He will provide the welcome and overview only.
Fumilio ario is an associate director within the office of budget finance and acquisition.
She will provide the update on the 5 year financial plans for.
Basufah engadoufa Valerie Overton and ayasha berland.

Valerie is a senior advisor and ayasha is a project manager at the eastern region research group.
They will provide an independent evaluation.
Of resource capacity planning capability.
Josh Barton Josh is the director of resource capacity planning staff within the center of drug evaluation and research.
He will discuss resource capacity planning implementation updates.
Sleep.
And now I would like to welcome Benjamin Marcus the FDA CFO to be able to give welcome and overview.
Good morning and thank you for joining us today.
Happy last day of the fiscal year and happy end of the year.
Hope all are doing well today.
Today is quite the day to have this this meeting.
Thank you for joining us today.
And hello to everyone in person here with us in the great room those who joined us via teams and those and everyone tuning in on the FDA YouTube channel my name is Benjamin monkharz.
I am the chief financial officer.
For the FDA I'm excited to be here today with you.
This annual meeting is part of FDA 's commitment under pdufa 7 pasufa 3 and gudufa 3 to enhance transparency in the financial management of user fee resources.
These user fees were reauthorized as part of the FDA user feed reauthorization act of 2022 signed on September 30th 2022.
This year we're really excited to provide an update on the significant amount of work that FDA has really invested to further strengthen our ability to efficiently utilize available program resources and to really display our level of effort and efficiency when it comes to managing these programs.
I would now like to introduce Oliver milio Rio who will who will cover an update on the 5 year financial plans olufmilayo.
Thank you Benjamin and good morning to everyone.
My name is olufim lieer ario and I am an associate director within the office of finance budget and acquisition and I'll be presenting an update on the 5 year financial plans for the human drug programs for each user fee program we have provided actuals for fiscal years 20.

3 and 24 total budgetary resources.
Obligations and carryover we have also included plan estimates for fiscal years 2025 to 27 reflecting the projected.
Financial position for the remainder of the current reauthorization period.
These plan estimates are reviewed and updated annually on actual collections and obligations from the prior year.
They serve as the baseline for future adjustments and are refreshed each year to cover the remaining years in the reauthorization period.
FDA uses appropriate user fee collections along with non user fee appropriations to hire support and maintain staff needed for the review.
Of human drug product submissions.
The first user fee will be discussing today on the slide.
Is to Purdue for 7 Purdue for 7 speed structure consists of 2 components?
Application fees and program fees target revenue totals presented here.
I've been fully calculated as defined by statue through fiscal year 26 and serve as the basis for setting the fee amounts 80% of this amount is allocated to be collected from program fees and 20% from application fees.
Total carryover represents unspent Purdue for funds at the start of a fiscal year including both available and unavailable balances.
End of year carryable balances become the next year 's beginning balance.
FDA generally assumes for planning purposes the net collections were equal to total.
Target revenue amount in practice net collections may differ from annual target revenue amount if the actual amount of fee paying units differ from the number of fees paying units estimated when fees are set each year.
The pdufa net collections estimate for fiscal year 25 reflects the projections used to determine the anticipated carryover balance when setting fees for fiscal year 26.
Based on a rate of collections year to date and historical trends FD expects to slightly under collect Purdue for fees in fiscal year 25 Purdue for fiscal year 25 estimated collections are 1.5 billion.
With future year recoveries estimated to be 15.8 1,000,000 annually.
Purdue for fiscal year 25 beginning of the year.
Carryover is 297.4 1,000,000 combined with the estimated collections and recoveries which brings the total budgetary resources to 1.8 billion.
The.
Second table shows the actual expenditures for fiscal year 23 actual and previously

planned expenditures for fiscal year 24 and plan expenditures for 25 through 27 of pdufa.
Funds broken out in major expense categories which include payroll operating rents and shared services costs.
Pdufa fees may be expended only for the cost to support the process for the review of human drug applications.
As defined in pdufa 7.
The estimated total obligations for 50 year 25 funded by pdufa.
Fee funds amount to 1.4 billion.
Lastly for pardewa.
Purdue for carry over table includes the estimated amounts for fee fees collected and not obligated at the end of the fiscal year 78.9 1,000,000 in fees collections from previous years are unappropriated.
Therefore are currently unavailable for obligation.
FDA sets aside meant set aside and maintains 30,000,000 in fee funds for refunds for 50 year 25 and out years therefore the estimated fiscal year 25 carryover net of what is unavailable and set aside is 270 1,000,000.
Turn into the biosimilar user fee act of Basu for 3.
It also covers the actual expenditures for fiscal year 23.
And previously planned expenditures for 24 and plan expenditures for 25 through 27.
The first table connects the target revenue to the net collections while showing the estimated total budgetary resources for each year.
We have total estimated budgetary resources for 50 year 25 for basufa program of 79.3 1,000,000 total estimated obligations of about 52,000,000 with estimated carryover net of the set aside funds for funds for refunds of 26,000,000.
Lastly for basufa it is important to note that basufah application submissions have been high over the past few years leading to significant collections and increased workload.
This trend resulted in a capacity planning adjustment of 2.7 1,000,000 in fiscal year 25 and might require future adjustments to operating reserves.
Next is the 3rd reauthorization of the generic drug use fee amendments or go do for 3 for fiscal year 25 go to first projected to have 705.8 1,000,000 in total budgetary resources.
Which includes 89,000,000 in unspent fee funds carried into the year 607.8 1,000,000 in estimated collections and 9,000,000 in annual recoveries?

We have estimated obligations of 579.4 1,000,000.
After accounting for obligations and a refund set aside the net carryover balance for fiscal year 25 is estimated at 120 1,000,000.
Go do first Fisher 25 collections estimate reflects the projected projection used to determine the anticipated carryover balance when set in fees.
For the 5th year 26 like the other programs based on a rate of collections year to date and historical trends FDA expects to under collect the due for fees in 25.
At this time there are no other significant financial impacts to highlight for godiva.
Thank you for your time.
Next we have eastern research group who will be presenting their findings for their independent assessment of resource capacity planning.
Their report was published on the FDA website.
On Friday September 26.
In addition their presentation satisfies a user fee commitment for fiscal year 26 thank you.

OV **Overton, Valerie *** 11:35
Thank you lucum milao for that introduction.
As openly as indicated, my name is Valerie Overton from Eastern Research Group.
My colleague Ayesha Berland and I are pleased to be here today to present the results of our independent third party evaluation of FDA's resource capacity planning capability in support of the PDUFA BASUFO and KADOOFA programs.
Next slide please.
In this presentation this morning, I'll first begin with an introduction to the evaluation. I'll describe the key.
Objectives of the evaluation and the questions that we answered in order to address those key objectives.
And the methods that we used to develop and analyze the data and then develop our conclusions.
I'll then present a summary of our results.
In the form of answers to the assessment questions.
And their conclusions in the form of findings and recommendations. Next slide please.
So begin with that introduction.
As opposed to Malayo indicated, yes.

Next slide please.
Thank you Asufu Malayo indicated this third party independent assessment fulfills an FDA commitment for PDUFA 7, VASUFA 3 and GUDUFA 3.
The evaluation objectives are threefold. If you can Click to show the first objective, thank you.
You.
So the first evaluation objective was to evaluate the ability of the capacity planning adjustment methodology to forecast resource needs for the Paducah and GDOUFO programs.
So to be clear, the capacity planning adjustment methodology is the methodology that FDA uses to estimate.
The number of additional full time equivalents, or FT ES.
That's then translated into a dollar amount.
To perform the workload for the upcoming fiscal year for each of these UFA programs.
The methodology includes a set of workload drivers which are various types of submissions and meetings that human Drug Review program staff perform in order to review the applications and perform program work.
Those workload drivers are defined as a by statute, as what is being allowed to be included in the capacity planning adjustment methodology.
So part of that first evaluation objective to evaluate the ability of the capacity planning adjustment methodology to forecast resource needs also involved evaluating the scope of the workload drivers and their ability to represent the overall workload.
Of each of the over programs PDUFA Basu and Khadoofa.
The second objective of the evaluation is to evaluate.
The time reporting system and practices that FDA uses to generate the time reporting data.
Used in the capacity planning adjustment methodology and other aspects of FDA's resource capacity planning work.
And so we looked at the time reporting.
System and practices to identify any opportunities for enhancement.
You can click for the third evaluation objective please. Thank you.
The third evaluation objective is to examine the integration and use of FD as other resource capacity planning information beyond the capacity planning adjustment

methodology which is used for fee setting.
But it the additional resource capacity planning information that FDA provides.
For financial and operational management of the Purdue footprint and qdoufa programs, next slide please.
So in order to address those key objectives, ERG first developed a set of assessment questions that we would need to answer in order to have the information that we needed.
To address the evaluation objectives.
So for the first evaluation objective, which was evaluating the capacity planning adjustment methodology, the assessment questions are to what extent has.
The capacity planning adjustment methodology approximated actual changes in FDA workload from the inception of the methodology to the present.
To what extent have the workload drivers in the capacity planning adjustment methodology represented actual UFA program work from inception to present for each of the UFA programs PDUFA, VASUFA and QDOUA?
And in what ways might those workload drivers change in upcoming PDUFA qdufa years?
And how might those changes impact the performance of the capacity planning adjustment methodology in forecasting resource needs for those programs?
You can click for the next set. Please. Thank you.
So the second evaluation objective had to do with FD as time reporting system and practices.
And so here the question is just that what if any changes to FD as tone reporting system or practices would improve its forecast of resource needs for the PDUFA Passover and programs?
And if you can click for the third.
Thank you.
For the third evaluation objective, we're just looking at more broadly at FD, as resource capacity planning capability for financial management. Of the PDUFA, PDUFA and PASUPA programs.
The assessment question are, first, how does FDA use its resource capacity planning capability for resource and operational decision making?
For those programs.
And then what, if any, changes to FDA's resource capacity planning capability would improve resource forecasts and information for operational decision making for

PDUFA, QDOUFA and BASUFAH. Next slide, please.
So in order to.
Fulfill this evaluation and the objectives.
We first developed an evaluation design and that consisted of establishing the assessment questions that I just described and then establishing a set of evaluation metrics.
Which represent the various kinds of data that we would need in order to answer those assessment questions.
We then created a set of data collection protocols and instruments to guide the collective, the comprehensive, accurate.
Systematic, methodical collection of the data that we would need for those metrics.
We then entered our data collection phase and for that we conducted interviews and collected qualitative and quantitative data.
On a wide range of topics related to the capacity planning adjustment methodology and the resource capacity planning.
Capability more broadly.
So that included all of the different kinds of inputs into the capacity planning adjustment methodology.
The results for each step in the methodology and of course the results of that methodology.
And the various models and information that.
FDA produces, as other aspects of its resource capacity planning capabilities.
We also looked at all of the documentation for these methodologies and obtained publicly available data to look at how FDA describes the methodology and the results.
So we collected all of this information for the period of fiscal year 2021 through fiscal year 2025.
And I just also wanted to add my appreciation and thanks to all of the many FDA staff who were very gracious and generous in responding in a very timely manner to our request for data interviews and other meetings.
Based on all of the data that we collected, we then conducted quantitative and qualitative analysis.
And interpreted all of those results in order to develop our conclusions in the form of answers to the assessment questions and finding some recommendations.
Next slide please.

So now we'll talk about.
The our results in the form of answer C assessment questions. Next slide. Thank you.
So go through for each evaluation quest, each evaluation objective and.
Each assessment question for those objectives.
The first being to what extent has the capacity planning adjustment methodology approximated actual changes in FDA workload from the inception of the methodology to the present?
And here what we found is that the capacity planning adjustment methodology has produced quite accurate resource need for CAAS as measured by.
Full time equivalents, which are then translated into dollar amounts.
Forecasting workload is notoriously challenging and can be quite complex.
And what we found is that the methodology that FDA has developed produces forecasts that fall within 10% of the actual values.
Each year and so we looked at the forecasted resource needs and then after the fiscal year is completed, what the actual.
Well, values work and so.
To produce forecasts that are within 10% of actual values is actually quite strong, and so we considered the CPA methodology.
To be quite accurate in approximating actual changes in FDA workload.
So I mentioned the ERD developed a set of evaluation metrics.
That our core metrics included nine items.
Of those nine, we rated the capacity planning adjustment methodology very high for seven and high for two. So for the seven that we rated as very high for the capacity planning adjustment methodology, they were accuracy, the breadth of coverage of the methodology.
That defensibility of the methodology, that feasibility of the methodology, the stability and the predictability of the results and the flexibility of the methodology to handle potential changes.
Those all received very high ratings.
Two evaluation metrics, straightforwardness and transparency, received high ratings.
And the difference between high and very high were just some minor issues.
These were not.
Kind of foundational issues, but fairly minor issues, which is why.
We brought it down to a high rather than very high rating and the reasons are the following. For straightforwardness, we acknowledge that workload forecasting is

inherently.
Complex.
What we found is that the capacity planning adjustment methodology is somewhat complex, but only to the extent that it's required to obtain accurate workload forecasts. That is, it was not more complex than was needed to produce the accuracy that is required.
And so therefore we gave that a high rating for transparency. The documentation that we reviewed is quite complete, comprehensive, accurate.
So strong in most ways.
The issues that we found were quite minor.
We found that the documentation could benefit from consolidation, improved formatting and some clarifications, and so we still gave that a high rating. Next slide please.
The second question is to what extent have the workload drivers and the capacity planning adjustment methodology represented actual UFO work for each of the UFA's? Pdufa, Vasufa and gadufa?
And here we found that the workload drivers, which as I mentioned are this mission types and meeting types that are statutorily allowed to be included in the methodology.
These workload drivers are reasonably good representation of the overall workload for each of the UFO's.
We found when we looked at the proportion of the total UFA hours.
That are represented by the workload drivers, that those are quite consistent year over year, fluctuating by 4% or less.
That consistency in the proportion of the hours represented by the workload drivers compared to the overall UFA hours is what makes these workload drivers a a good representation of overall workload. Next slide.
Please.
The third assessment question was in what ways might the workload drivers change in upcoming years, and how might those changes impact the performance of the capacity planning adjustment methodology in forecasting resource needs for each of the UFA programs?
And here what we found is that the methodology is sufficiently flexible to address the types of changes.
That we might anticipate.

For example.
It can accommodate changes, additions, deletions of workload drivers if necessary.
It can accommodate changes in the relative volumes of different types of submissions.
New account codes and FDA's time reporting systems.
Should there be a need for different types of activities to be recorded?
It can also accommodate unforeseen changes in submission volume or a change in the average cost of review staff.
For example, if there is a need for a different mix of expertise or types of staff, that changes the average cost.
It can accommodate those kinds of changes by means of the final step in the methodology, which is the managerial adjustment.
So again this the flexibility of the capacity planning adjustment methodology suggests that it will continue to perform well over time.
Next slide please.
So for the 2nd valuation question, which was about FDA's time reporting systems or practices, the second question was what, if any changes might?
Improve.
FDA's forecast for resource needs for Ital programs.
What we found is that FDA has already modernized its time reporting system and practices, and that the system and practices.
Produce accurate data.
For management of the PDUFA and QDOUFA programs for management and resource forecasting.
So we found no need for changes.
FDA encourages staff to report their time on a daily basis.
And require staff to report their time by the end of each two week pay period.
The reason why?
They encourage, but do not require daily reporting.
Is that that would be burdensome for some types of staff with some roles where the variety of activities.
Would create some burden in terms of daily time reporting.
So we we certainly as FDA is doing encourage the practice of daily time reporting which tends to generate the most accurate and reliable time reporting data.
To the extent that FDA is able to encourage more staff to report time on a daily

basis, that might prove generate modest incremental improvements in the accuracy and reliability of the time reporting data.
I mentioned that the data are already quite accurate and so any improvements would be modest because the data are already quite strong. Next slide please.
So the next the third evaluation question was about FD as resource capacity planning capability.
Beyond the capacity planning adjustment methodology for fee setting, but rather for other types of resource and operational decision making.
Management of the various UFA programs.
So we found that FDA uses its resource capacity planning capability in a variety of ways.
For example, to quantify the use of resources and to forecast resource needs in specific offices and divisions. So not just at the overall.
UFA level for prud.
Or center level, but for specific offices and divisions.
And so that, of course, is based on past, present and future trends and fluctuations and workloads.
The resource capacity planning staff produced both recurring and ad hoc on request reports and models.
For understanding and managing resource needs at the office and division level for some offices and divisions.
And of course, to support financial management of each program. So for example, the resource capacity planning staff produce process cost percentages.
Which are just the percentage of total cost that individual processes represent.
And so understanding the overall cost and what the cost of individual processes are helps to support budgeting, implementation and financial management of these programs.
Next slide please.
So the next question is, what, if any, changes to FDA's resource capacity planning capability would improve FDA's resource forecasts and operational decision making processes for each of these FA programs?
And here we found that FDA's resource capacity planning team are already.
Working on maturing their capabilities and expanding what they do.
To support the needs of the centers and offices.
So, for example, FDA has developed some useful models for some of the offices to

improve resource and operational decisions.
And it is already planning to and working on continuing to replicate or adapt these models for other offices.
And also to facilitate ongoing improvements to existing models.
The resource capacity planning team has already been providing FDA.
These technology teams.
With requirements and needs for what?
Nexus and Cedar one the larger kind of analytics and hosting data platforms.
And and we'll continue to to do that.
So these these are not so much changes as just ongoing efforts that will continue to enhance.
The resource capacity planning capability.
Next slide please.
And then the last assessment question is, what, if any changes to FD as resource capacity planning capability would improve its utility for other operational decision making. And as I indicated, the resource capacity planning team is already been kind of proactively scanning the environment for opportunities for improvement.
Talking with the center and offices and divisions.
About their needs, the FDA technology teams and so forth.
Their their capabilities, their the information and models that they produce are widely accepted as accurate.
They're based on strong methodology and so we did not identify a need for changes.
Next slide please.
So now I'll talk about how we kind of synthesized all of that into a set of findings and recommendations.
We divided the fundings and recommendations into categories. The overarching overall applicable to all ufas, and then Ufa specific. So the first overarching.
Finding is that the capacity planning adjustment methodology performs well in forecasting resource needs and the scope of the workload drivers in that methodology are a good representation.
Of Oofa workload and so no action is needed.
You can Click to for the next finding. Thank you.
The second finding is that while FDA maintains complete, thorough and accurate documentation.
For the capacity planning adjustment methodology, further organizing and

streamlining the documentation could benefit resource capacity planning staff, especially those new to the methodology.
And here are the recommendation. As I indicated earlier, it's really kind of minor in nature.
This is not kind of any kind of foundational problem, but kind of minor enhancements that could make the documentation just easier and more useful.
So here we recommend consolidating and standardizing the format of the documents, adding visual aids to show relationships to the steps in the methodology.
Standardizing and defining terms and adding version numbers and dates to track updates.
Next slide please.
The third overarching finding is that the time reporting system is easy to use, flexible, and it provides accurate time reporting data.
FDA encourages daily reporting and requires that hours are reported at the end of each two week period.
And here the recommendation is really more of the same. Again, to continue to encourage daily time reporting.
While allowing for flexibility for staff for whom this would be burdensome.
And possibly exploring the idea of sending daily reminders to staff close to the end of the business day.
If you can click for the next finding. Thank you.
We also found that resource capacity planning use for financial planning as well established and functioned well. No action needed.
Next please.
Thank you.
Our next overarching finding is that FD as resource capacity planning capability is well positioned to meet future needs for resource and operational decision making with the following efforts.
That the team again is already continuing to work on and enhance.
Use of reports and data-driven resource forecasting models.
For resource planning and operational decision making.
Development of analytical models for more efficient and effective regulatory operations.
And providing FDA technology teams again with the needs and suggestions.
As they build that those centralized analytical environments, cedar one and migrate

to a centralized workflow management platform which is one Nexus and here the recommendations are really.
Items that the resource capacity planning team is already working on or planning.
So that is to incorporate minor improvements to resource forecasting models as recommended by users.
Determine how similar models might be incorporated by other Cedar and Saber offices for operational and resource decision making.
Continue developing analytical models and simulation approaches and supporting efforts to migrate processes and data.
To cedar one and one Nexus, next slide please.
So now I'll talk about a couple of specific UFO specific findings.
The first is for PDUFA.
Here what we found is that Cedars resource capacity planning capability is quite mature and Siebert is working on maturing its capability.
And no action is needed.
This is simply an observation because Siebert is already working to mature its resource capacity planning capability.
And click for the next one please.
And this next one is for vasufa.
So again, we found that the capacity planning adjustment methodology performs well for all three of the UPA's PDUFA BASUFA and GADUFA for PASUFA in particular.
Compared to PDUFA and GDUFA, there's a relatively smaller volume of submissions.
And until recently, a lack of historical data.
For those two reasons.
And not because of any flaw in the capacity planning adjustment methodology, but for those two reasons, the capacity planning adjustment methodology for PASUPA has tended to under forecast.
Workload.
And so the recommendation here is again something that the resource capacity planning team is already planning and working on and that is to revisit the VASUFA models and methodologies. Now that FDA has more historical data.
Next slide please.
So that is kind of a summary of the results of our evaluation.
As often Malayo indicated earlier.
The our full report is published on FD as website and that has a lot more details.

So with that, thank you for your attention and I'll transition to Josh Barton, who is the director of Cedars resource Capacity Planning team and he will deliver FDA's response to this evaluation.
Thank you.

42:43
Thanks Valerie and thanks everyone for joining us today.
You know I realized while I was sitting here that today represents a significant milestone for resource capacity planning not just because the erg report represents significant commitments for the current authorization period but it was actually 10 years ago.
During the pdufa 6 negotiations in the fall and winter of 2015 that this concept and the idea of a resource.
Driven resource management capability was aligned on between the FDA and industry and the pdufaics negotiations.
As soon as those negotiations were wrapped up I started working on figuring out how to transition this vision into practice.
We brought on pricewaterhouse Coopers R&D pharma sector R&D operations practice to help help us build on.
Existing best practices in the industry tailor those to the FDA.
And then we started building the staff to fully insource the capability.
And so we've come a long way over the last 10 years.
I like to thank my staff for everything that they've done as well as the sieber staff.
And the FDA leadership for the continued support and utilization of the RRCP outputs.
So.
What I'll do is I'm going to walk through a quick FDA response to the findings and recommendations from the erg study I want to thank erg for about a year of digging through a significant amount of data?
We recognize that this is a resource capacity planning and the models are are somewhat complex and appreciate their efforts so I'll run through the findings recommendation slides that erg had with a short FDA response in a.
Blue call out.
So the first finding the CPA performs well in forecasting resource needs we we agree.
Well erg says.

No action needed I'll note that we are always dedicated to continual improvement and are always continuing to reassess our data and our models and improve upon the model.
Performance I think Valerie noted that the outputs are consistently within 10%.
Of actual values.
When we're working back with PwC they indicated that?
The the benchmark in the industry was about 15%.
So we're really proud to keep those numbers within the 10% consistently.
So the second recommendation regarding documentation and some of the formatting the documentation a lot of this reference documentation is intended for internal use.
So folks are very familiar with it document processes and decisions.
But will we will review opportunities to consolidate and update formatting as appropriate.
We'll recognize that.
Regarding time reporting and continuing to encourage daily time reporting.
We agree.
We we have and we will continue to encourage daily time reporting.
And really considering the optimal ways of supporting staff in timely entry of their time reporting data.
While also maintaining an appropriate balance for our staff as they have many other important things to do.
RCP used for financial planning as well established we agree.
Recognize we've come a long way in developing a culture around using data to help inform resource management and allocation and.
And those processes internally over the last 10 years.
So regarding.
Meeting the future needs for resource and operational decision making.
Developing.
Continuing developing analytical models simulation approaches you know as noted we are dedicated to continual improvement of our outputs in support of efficient and effective regulatory operations for internal parties.
We will continue to support offices as appropriate with modeling solutions as as our resources allow you know.
I think we've seen over over the last years that the most valuable efforts are when we

can work with an office internally that has a specific challenge or issue and really develop a fit for purpose.
Solution for them or develop a model or some analysis to help them with their specific challenges or issues.
And we'll continue to support the we will continue to support the continued development of the the cedar one analytical platform which will continue to help enable efficient model delivery.
Regarding siebert working to make sure its RCP capability we agree.
We collaborate closely between cedar and siebert on resource capacity planning.
Regarding the basufah models and recommendation to revisit those models we've already begun implementing a new generation of more mechanistic models for the basuva program.
Given the continued the ongoing history the Basu Fer program and.
The the growth of that program and the additional data that we collect year over year.
So we're seeing promise there already.
And I think that's all I have for you.
So thanks for your your attention and I'll turn this to kisha thanks.
Thank you Josh and thank you to all of our presenters today as well as to all in person and virtual attendees before we depart I have a few follow up pieces of information to share with you.
In accordance with the Federal Register notice we are now entering the open.
Public comment period where individuals will have the opportunity to provide comments to the FDA.
There is a public docket that will be open until October the 30th at 11:59 PM Eastern Time to which anyone can submit questions to submit questions please visitregulations.gov use the docket number FDA dash 2019.
N 1875 to locate the meeting submit your comments as a reminder your comments will be documented as a part of the public record if you would like to access today's materials.
They will be posted from this meeting on the FDA web page shortly.
Thank you all for attending today's meeting and I hope that you have a wonderful and restful day.
And we're done.

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