WEBVTT

1
00:00:32.280 --> 00:00:44.160
Monica.Ellerbe@fda.hhs.gov: Good morning, everyone we're going to go ahead and get started with our meeting today, so the morning again and my name is Monica or B and I serve as the director of business management services, but then the FDA is office of finance.

2
00:00:44.760 --> 00:00:50.280
Monica.Ellerbe@fda.hhs.gov: acquisitions and planning, welcome to this year's public meeting all financial transparency and efficiency.

3
00:00:50.520 --> 00:01:03.720
Monica.Ellerbe@fda.hhs.gov: Of the prescription drug use of the Act bar similar use of the Act and generic use drug use of the amendments, I would like to now take this time to introduce our CFO J Tyler to provide an overview and a welcome for today's meeting.

4
00:01:09.180 --> 00:01:19.920
James.Tyler@fda.hhs.gov: Thank you, Monica and good morning everyone again, my name is James J Tyler and i'm the CEO CFO and head of the office of finance budget acquisitions and planning.

5
00:01:20.400 --> 00:01:34.710
James.Tyler@fda.hhs.gov: At FDA This is our annual meeting as part of the commitment that FDA made under paducah six but super to end to do for to enhance transparency and management about user fee resources.

6
00:01:35.460 --> 00:01:42.480
James.Tyler@fda.hhs.gov: This year the FDA is excited to provide an update on the significant amount of work that the Agency has invested in.

7
00:01:43.110 --> 00:01:54.120
James.Tyler@fda.hhs.gov: With respect to strengthening our ability to efficiently utilize our available user fee program resources, this morning I want to take a few minutes to go over our agenda.

8
00:01:54.630 --> 00:02:07.380
James.Tyler@fda.hhs.gov: So today, a few of my FDA colleagues will discuss related topics in terms of the transparency and efficiency of the human drug user fee programs you're here from brandon Lee.

9
00:02:07.800 --> 00:02:16.350

James.Tyler@fda.hhs.gov: brandon is a supervisory operations research analyst within user fee support staff at the office of finance budget acquisitions and planning.

10
00:02:17.010 --> 00:02:22.020
James.Tyler@fda.hhs.gov: He will provide an update on the five year plans for paducah but super and good do for.

11
00:02:22.770 --> 00:02:33.270
James.Tyler@fda.hhs.gov: josh Barton josh is the director of resource capacity planning at the office of program and strategic analysis within the Center for drug evaluation and research.

12
00:02:33.750 --> 00:02:42.630
James.Tyler@fda.hhs.gov: josh will provide an update on the implementation of the resource capacity planning capability and discuss the capacity planning adjustment methodology.

13
00:02:43.680 --> 00:02:52.710
James.Tyler@fda.hhs.gov: And Andy kish is the director of the office of program and strategic analysis within cedar or the Center for drug evaluation and research.

14
00:02:53.460 --> 00:03:05.550
James.Tyler@fda.hhs.gov: And Andy will touch upon resource capacity planning as communicated in the Federal Register notice, you will have the opportunity to provide public comment to the FDA at the end of the meeting.

15
00:03:06.060 --> 00:03:21.510
James.Tyler@fda.hhs.gov: Your comments will be documented as part of the public record the public document is open until July seven for the public to submit comments, without further ado, I will turn it over to brandon to provide an update on the five year plans, thank you.

16
00:03:23.700 --> 00:03:34.230
Brandon.Lee@fda.hhs.gov: Good morning, everyone Thank you Jay my name is brandon Lee with the FDA office of finance budget acquisitions and plan i'll be providing the update on the five year financial plan for the human drug programs.

17
00:03:35.010 --> 00:03:39.060
Brandon.Lee@fda.hhs.gov: To start, I would like to provide some additional context for the five year plans.

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00:03:39.510 --> 00:03:45.960
Brandon.Lee@fda.hhs.gov: One of the things with the five year plans is that the FDA cannot obligate any funds in advance of receiving those funds.

19
00:03:46.350 --> 00:03:54.930
Brandon.Lee@fda.hhs.gov: And since fyi 22 is the current year right now is last year, the current authorization period for the super good do for an interview for.

20
00:03:55.770 --> 00:04:12.720
Brandon.Lee@fda.hhs.gov: The authorization period expires at the conclusion of fyi 22 which will be September 30 this year we're currently waiting for the reauthorization of the program big oceans between the industry and FDA have been complete and the reauthorization packages are with Congress at this time.

21
00:04:14.070 --> 00:04:22.800
Brandon.Lee@fda.hhs.gov: Since the current programs are set to expire and are pending reauthorization at the time of the publication of our five year plans the FDA cannot.

22
00:04:23.370 --> 00:04:38.430
Brandon.Lee@fda.hhs.gov: project, the financial position of the programs after until after the authorizations have been approved, so the recently published five year plans which you can find on the FDA website are limited to the end of this authorization period.

23
00:04:41.190 --> 00:04:53.880
Brandon.Lee@fda.hhs.gov: The FDA does not expect a lot does expect many of the recent external factors that have been impacting the programs in the past five years to continue to impact those programs in the coming years.

24
00:04:54.360 --> 00:05:00.690
Brandon.Lee@fda.hhs.gov: This includes the continued high level of workload resulting from industry submissions the.

25
00:05:01.350 --> 00:05:15.690
Brandon.Lee@fda.hhs.gov: potential impacts, due to the October 19 pandemic, as well as the continued competition for the new necessary scientific and technical talent needed to deliver on the performance commitments and the related public health priorities.

26
00:05:17.190 --> 00:05:20.550
Brandon.Lee@fda.hhs.gov: So Turning first to the.

27
00:05:21.840 --> 00:05:30.420
Brandon.Lee@fda.hhs.gov: First, financial five year plan looking at purdue, for this is the sixth authorization of the prescription drug user fee activity for sex.

28
00:05:31.350 --> 00:05:41.220
Brandon.Lee@fda.hhs.gov: belief, has to do for has three legal conditions or triggers that must be met in order to spend and use any user fees collected or fyi 22.

29
00:05:41.640 --> 00:05:46.410
Brandon.Lee@fda.hhs.gov: F like 21 in the previous year, the FDA did in fact meet each of the triggers.

30
00:05:47.190 --> 00:06:06.060
Brandon.Lee@fda.hhs.gov: And in fyi 21 the FDA does have a net collection of $1.153 billion in user fees and spent $1.109 billion for the human drug review process and are we are carrying 240 $5 million of user fees forward for future fiscal years.

31
00:06:08.520 --> 00:06:17.280
Brandon.Lee@fda.hhs.gov: Under producer six GPA, is implementing numerous commitments made under the user fee agreement, as well as new programs mandated by Congress and saddar.

32
00:06:18.210 --> 00:06:29.130
Brandon.Lee@fda.hhs.gov: The FDA is continuing to make significant progress and implementing many of the commitments made, including enhancing patient input integrating it in the regulatory decision making.

33
00:06:29.700 --> 00:06:45.960
Brandon.Lee@fda.hhs.gov: Enhancing regulatory science using real world evidence expediting expediting drug development enhancing benefit risk assessment in regulatory decision making and many of the other commitments made under doofus six.

34
00:06:47.340 --> 00:06:49.080
Brandon.Lee@fda.hhs.gov: Overall I the end of.

35
00:06:50.940 --> 00:07:01.200
Brandon.Lee@fda.hhs.gov: To do for net 27 other commitments and did meet and this to have the commandments during the fiscal year but to miss commitments include the paducah hiring goal.

36
00:07:01.740 --> 00:07:14.580
Brandon.Lee@fda.hhs.gov: And the publication of patient focused drug development guidance to incorporate clinical health home assessments into endpoints further information about these two minutes and others can't and other information can be found in the.

37
00:07:16.140 --> 00:07:17.010
Brandon.Lee@fda.hhs.gov: Performance report.

38
00:07:20.970 --> 00:07:35.790
Brandon.Lee@fda.hhs.gov: Turning next to the SOFA, this is the second authorization under the bio similar user fee act or receive achieve this is the ninth that report under the SOFA and the second and the fourth under the second authorization.

39
00:07:36.870 --> 00:07:47.310
Brandon.Lee@fda.hhs.gov: And fyi 21 we super had to legal trigger triggers and the FDA did meet both of them or the authorization to collect and spend user fees.

40
00:07:48.930 --> 00:08:05.580
Brandon.Lee@fda.hhs.gov: The super user fees and non user fee appropriations math like my one support approximately 155 full time equivalents, including the salaries and operational expenses to support the process for the review of ios similar biological product applications.

41
00:08:07.410 --> 00:08:23.430
Brandon.Lee@fda.hhs.gov: In F1 fyi 21 FDA had net collections of $43 million and the super fees and spent 3034 million of those fees for the super program and will be carrying forward 46 million into future fiscal years.

42
00:08:25.350 --> 00:08:34.320
Brandon.Lee@fda.hhs.gov: As part of the sukkah to FDA will continue to facilitate the development of bio similar biological products, including interchangeable biosimilars.

43
00:08:34.830 --> 00:08:44.340
Brandon.Lee@fda.hhs.gov: Through the strategic development of FDA bios and more biological product review program and through an ongoing clarification of the approval pathways for these products.

44
00:08:46.530 --> 00:08:53.340

Brandon.Lee@fda.hhs.gov: In the sukkah to commitment letter FDA committed to enhancing the cassie for bio similar regulations and guidance development.

45
00:08:53.850 --> 00:09:07.410
Brandon.Lee@fda.hhs.gov: reviewer training and timely communication, as well as strengthening step asking deliver information concerning the data first licensed in her and reference product exclusivity expiring date.

46
00:09:07.950 --> 00:09:26.310
Brandon.Lee@fda.hhs.gov: To be included in the purple book as committed through the first four years of vicissitudes FDA has enhanced capacity to address these important elements will continue to work and develop those products and update the purple book throughout this next upcoming year.

47
00:09:27.750 --> 00:09:28.410
Brandon.Lee@fda.hhs.gov: The.

48
00:09:29.880 --> 00:09:30.750
Brandon.Lee@fda.hhs.gov: There were.

49
00:09:33.210 --> 00:09:44.040
Brandon.Lee@fda.hhs.gov: 27 performance gold categories that apply for the fly 21 total for the super program we base off with the preliminary information that we have for the year.

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00:09:44.760 --> 00:10:04.590
Brandon.Lee@fda.hhs.gov: The FDA will meet or exceed at least 16 of the 27 goals that information will be finalized, but the information of those goals can again be found in be on our website, if you go to fca.gov and look for user fee, you can find our five year plan, as well as a performance plans.

51
00:10:12.960 --> 00:10:22.770
Brandon.Lee@fda.hhs.gov: Turning to the last program that we are going to be covering will be the second authorization of the generic drug user see act or getting fetching, this is the.

52
00:10:24.570 --> 00:10:31.110
Brandon.Lee@fda.hhs.gov: Financial report and five year plan for two new thought, and the second and the fourth one under the current authorization period.

53
00:10:32.340 --> 00:10:39.030

Brandon.Lee@fda.hhs.gov: To do for has three legal conditions that have to be certified which the FDA man, all three, four and 521.

54
00:10:40.020 --> 00:10:59.220
Brandon.Lee@fda.hhs.gov: In fyi 21 the FDA did have a collection of $500 million in human generic drug user fees spent 536 million in user fees for the human human generic drug review process and carried 120 $7 million forward for future fiscal years.

55
00:11:01.230 --> 00:11:12.840
Brandon.Lee@fda.hhs.gov: Under to do for to FDA continues to monetize the generic drug program by focusing efforts on improving the efficiency, quality and predictability of the generic drug review process.

56
00:11:13.950 --> 00:11:26.250
Brandon.Lee@fda.hhs.gov: Moving forward the FDA will continue to expand upon these improvements made in particular in the areas of strengthening development and review of hard to general generic sized complex products.

57
00:11:26.970 --> 00:11:38.760
Brandon.Lee@fda.hhs.gov: continued support and development of business processes to increase first cycle reviews and to reduce the time of approval by increasing communication and collaboration between the FDA and industry.

58
00:11:39.630 --> 00:11:53.070
Brandon.Lee@fda.hhs.gov: Also, looking to continue implementation of FDA drug competition action plan which focuses on developing and implementing initiatives further expedite the availability of generic drugs.

59
00:11:57.360 --> 00:11:58.890
Brandon.Lee@fda.hhs.gov: In many of these.

60
00:12:00.120 --> 00:12:17.430
Brandon.Lee@fda.hhs.gov: In each of these user fee programs, we have been implementing and continue to grow and develop the toss reporting capacity planning and the time reporting structures and information captured for each of these with that.

61
00:12:20.220 --> 00:12:29.220
Brandon.Lee@fda.hhs.gov: There have been changes across all of the human drug programs, in particular, the changes to the fee program to improve the stability, predictability of funding.

62
00:12:29.670 --> 00:12:39.780

Brandon.Lee@fda.hhs.gov: improved efficiency by simplifying the administration of user fees and enhanced flexibility of the financial mechanisms to improve the management of program funding.

63
00:12:43.440 --> 00:12:47.250
Brandon.Lee@fda.hhs.gov: to further expand and talk about those changes and the.

64
00:12:48.630 --> 00:12:55.950
Brandon.Lee@fda.hhs.gov: methodologies that we have put in place the next presenter my colleague josh barn will be presenting on the resource capacity planning, implementation.

65
00:13:06.150 --> 00:13:10.320
Joshua Barton: Thank you brandon and thank you to everyone for joining us this morning.

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00:13:11.400 --> 00:13:22.050
Joshua Barton: i'm going to speak to two topics, given that this is the fifth and final year of the current authorization cycle we'll do a quick recap of.

67
00:13:22.770 --> 00:13:32.220
Joshua Barton: The resource capacity planning and modernized time reporting commitments and talk about how how we met those commitments and that and the progress that has been made on that front.

68
00:13:33.330 --> 00:13:44.340
Joshua Barton: Then i'll pivot to providing a little bit of a deep dive into the capacity planning adjustment methodology and then i'll turn this over to Andy kish to provide a quick recap.

69
00:13:48.030 --> 00:13:53.040
Joshua Barton: So first resource capacity planning or rcp progress review.

70
00:13:56.520 --> 00:14:08.730
Joshua Barton: So, as you likely know you're here this morning, if a SEC specific to and could do to all included a set of resource capacity planning and modernize time reporting commitments.

71
00:14:09.240 --> 00:14:17.790
Joshua Barton: For simplicity sake, we just have the the pedophile commitment letter language up here, but a language is similar across specific as well.

72
00:14:18.780 --> 00:14:30.840
Joshua Barton: The most notable difference was that the do for to program didn't provide for a statutory process to implement a capacity planning adjustment or fee adjustment methodology where paducah super did.

73
00:14:32.520 --> 00:14:43.050
Joshua Barton: So i'll spare you from me, reading the text here to you, but in some there's four specific amendments, the first being to publish an implementation plan.

74
00:14:43.650 --> 00:14:54.840
Joshua Barton: The second being to staff, a resource capacity Planning Team the third being to fulfill a process to establish the capacity planning adjustment methodology for paducah and the super.

75
00:14:55.620 --> 00:15:07.560
Joshua Barton: And the fourth around financial processes and reporting related to the capacity planning adjustment and we'll walk through each of these and and talk through how we met these each of these components.

76
00:15:12.450 --> 00:15:20.880
Joshua Barton: So the first the first commandment we had was to publish a resource capacity planning and modernized time reporting implementation plan.

77
00:15:22.620 --> 00:15:30.180
Joshua Barton: And the commitment included the specific requirement to bring in a third party assessment of resource capacity planning.

78
00:15:31.230 --> 00:15:38.850
Joshua Barton: Financial analytics and modernize time recording and tell them form the implementation plan and really the idea, there was to bring in.

79
00:15:40.200 --> 00:15:55.620
Joshua Barton: external experts to help inform and advise the FDA on leading practices in this area in informing how we approach the design and implementation of rcp within the FDA.

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00:15:58.470 --> 00:16:08.250
Joshua Barton: So, through a competitive process FDA hired Price Waterhouse Coopers PTC as a third party to assess and advice, the Agency.

81

00:16:08.880 --> 00:16:20.220
Joshua Barton: On its approach implementing our CP and modernize time recording the PTC team included their private sector, pharmaceutical and life sciences are indeed advisory services.

82
00:16:21.210 --> 00:16:29.430
Joshua Barton: Which is a practice that that typically works with many of the medium and large size pharmaceutical firms.

83
00:16:30.150 --> 00:16:43.980
Joshua Barton: And we worked with their existing integrated operations and business planning framework or I O BP as a starting point and then tailor that to fit the needs of these are free programs for the FDA.

84
00:16:44.820 --> 00:16:54.990
Joshua Barton: Well, there are some similarities and how we operate fair to the companies that we regulate there, of course, many significant differences in our operating paradigm.

85
00:16:55.740 --> 00:17:06.930
Joshua Barton: Perhaps most significantly, the fact that we, we are used a few programs aren't able to control the amount of review work that we do is where you need to be responsive to.

86
00:17:08.100 --> 00:17:12.450
Joshua Barton: The industry submitted submissions to the to the Program.

87
00:17:15.120 --> 00:17:24.450
Joshua Barton: So we work to align our approach to need to commitments my data new iot up to our operating paradigm, and we published our our approach.

88
00:17:26.070 --> 00:17:34.980
Joshua Barton: In our rcp and modernize time reporting implementation plan, which was published in March 2018 and which is still available on the FDA website.

89
00:17:40.890 --> 00:17:49.680
Joshua Barton: So the second commandment here with the staff, a resource capacity Planning Team that will implement and manage capacity planning system across the different programs.

90
00:17:51.510 --> 00:18:00.960

Joshua Barton: And we've established a resource capacity planning staff and cedar to help service a lead on our CP activities and we collaborate collaborate closely with our colleagues in cbre.

91
00:18:02.490 --> 00:18:15.930
Joshua Barton: there's also been a team established the headquarters level to support the implementation operations and maintenance of the insight insight time reporting application, which provides some of the modernized time reporting capabilities.

92
00:18:22.320 --> 00:18:37.470
Joshua Barton: The third commandment was around a process to establish the capacity planning adjustment methodology and, as noted earlier and video from the sukkah there is also a process I wanted statute to establish the capacity planning or CPA methodology.

93
00:18:39.060 --> 00:18:56.130
Joshua Barton: That process required us to contract with an independent accounting or consulting firm to evaluate options for capacity planning adjustment and an established process, including review of public comment before establishing the new capacity planning assessment methodology.

94
00:18:57.780 --> 00:19:06.480
Joshua Barton: So we the FDA commission to reports with booz Allen Hamilton to conduct to evaluations one focused on producing the sukkah.

95
00:19:07.410 --> 00:19:19.860
Joshua Barton: Given the similarity in structure and the statutory process to enable a capacity planning adjustment methodology or fee adjustment for those two programs, and then a second one for you to have.

96
00:19:21.390 --> 00:19:23.700
Joshua Barton: Both republishing fyi 2020.

97
00:19:24.930 --> 00:19:31.020
Joshua Barton: which generally endorsed the CPA methodology, while providing some considerations for feature enhancements.

98
00:19:37.980 --> 00:19:44.700
Joshua Barton: And the fourth commandment area was around financial processes financial processes and reporting.

99
00:19:45.240 --> 00:19:52.350

Joshua Barton: recognizing that the revenue generated by the workload adjuster and the resource capacity planning adjustment was replaced workload adjuster.

100
00:19:53.340 --> 00:20:04.800
Joshua Barton: will be allocated and used by organizational review components engaging direct review work to enhance resources and expand staff capacity and capability and that will document, the use of those funds and the annual financial reports.

101
00:20:06.090 --> 00:20:15.180
Joshua Barton: can be delivered on this by stashing internal processes to ensure the distribution of the revenue generated by the CPA about the interim and the the modernized CPA.

102
00:20:15.690 --> 00:20:22.110
Joshua Barton: are allocated to the review components consider and cbre and there's been documentation added to the annual financial reports.

103
00:20:28.080 --> 00:20:34.890
Joshua Barton: So, again just being the fifth and final year of the current cycle wanted to just provide that quick recap on.

104
00:20:35.910 --> 00:20:45.180
Joshua Barton: How we delivered on the letter and spirit of the commandments and the resource capacity planning and modernize time reporting space recognizing that.

105
00:20:46.470 --> 00:20:54.990
Joshua Barton: You know, there is a likely reauthorization coming but it's not finalized yet it's not the.

106
00:20:57.330 --> 00:21:06.300
Joshua Barton: Language has not yet been enacted but assuming reauthorization of the user fee programs as negotiated next steps and very general terms.

107
00:21:07.680 --> 00:21:12.390
Joshua Barton: would be to continue to deliver on the rsvp rsvp and related commitments.

108
00:21:13.500 --> 00:21:28.620
Joshua Barton: to continuously improve the existing rcp capabilities to articulate and updated our CP plan for the next authorization cycle and

to work to implement the CPA methodology for could do for as as negotiated.

109
00:21:32.220 --> 00:21:32.700
Joshua Barton: So that.

110
00:21:33.930 --> 00:21:37.410
Joshua Barton: catch my breath for a second and that that it's the.

111
00:21:38.610 --> 00:21:56.160
Joshua Barton: culmination of five plus years really six or seven years of work to to really envision and deliver on the establishment of this resource capacity planning capability, so I think everyone internally that's that's helped us move this forward both procedures cbre.

112
00:21:57.180 --> 00:22:00.780
Joshua Barton: And headquarters and others who have helped helped to.

113
00:22:02.520 --> 00:22:07.830
Joshua Barton: establish this capability as as we committed to, in the current authorization per cycle.

114
00:22:10.560 --> 00:22:19.200
Joshua Barton: All now pivot to the capacity planning adjustment methodology and i'll provide a little bit of a deep dive providing some of the.

115
00:22:20.040 --> 00:22:35.070
Joshua Barton: First, the historical context and a little bit of information on why capacity play adjustment exists and why it's important to the programs and then i'll provide kind of a walkthrough of the steps within the capacity planning adjustment process.

116
00:22:41.310 --> 00:22:48.900
Joshua Barton: So first just to kind of orient this this topic, a little bit in the history of the user fee programs.

117
00:22:50.550 --> 00:22:54.960
Joshua Barton: period, it was established, first in fiscal year 1993.

118
00:22:56.310 --> 00:23:01.140
Joshua Barton: To provide predictable and stable revenue to enhance staffing and infrastructure for the Program.

119
00:23:03.030 --> 00:23:07.170
Joshua Barton: That predictable and stable revenue was really an important theme.

120
00:23:08.760 --> 00:23:21.780
Joshua Barton: And an important aspect of the program it's really important to the program to have predictable and stable revenues, so that we know that we can hire staff and be able to continue to pay staff in the future.

121
00:23:24.000 --> 00:23:33.480
Joshua Barton: However, it was a little bit of a double edged sword, in that, in the initial design the program the annual fee revenue amount did not change, based on the industry some of that workload.

122
00:23:35.520 --> 00:23:43.500
Joshua Barton: So what that meant was that when when and if if and when industry submission volumes increased.

123
00:23:44.250 --> 00:23:52.290
Joshua Barton: FDA would have more review work that it had to complete under the same performance timelines the same financial and staffing resources.

124
00:23:53.100 --> 00:24:02.100
Joshua Barton: So, over time, a growth in the program workload, especially during predicted to became unsustainable continue to introduce that the meeting management goals.

125
00:24:04.860 --> 00:24:21.930
Joshua Barton: So to address this issue, industry and the FDA agreed to a mechanism to addresses this problem and do for three, which was a producer workload adjuster the potential workload adjuster was a mechanism that adjusted the annual fee revenue amount based on industry submissions.

126
00:24:24.120 --> 00:24:32.850
Joshua Barton: So, as established verse 34 three and then what's the subject of negotiations and third party studies following and pity for for me for five.

127
00:24:36.180 --> 00:24:52.950
Joshua Barton: up to five, one of the studies found that the workload adjuster was not optimal but likely the best feasible model available to

the at the at the at available to the FDA at the time, given the data and the the the infrastructure available that.

128
00:24:54.840 --> 00:25:07.290
Joshua Barton: So, in light of those findings and predict the six industry and FDA agreed on a set of commitments to establish a resource capacity planning capability which is really to build and improve that and data analysis infrastructure.

129
00:25:08.850 --> 00:25:22.050
Joshua Barton: And to to modernize our timer 40 approach so as noted the capabilities, would help were intended to help provide a better foundation for more optimal optimal revenue adjustment, amongst other things.

130
00:25:23.130 --> 00:25:33.630
Joshua Barton: The workload adjusted mechanism was renamed us capacity planning adjustment and the Statute provided for internal capacity plenty adjustment for paducah for the first couple of years of pity for six.

131
00:25:34.440 --> 00:25:42.720
Joshua Barton: As well as a process to establish a new methodology and to apply it to the super program as well, so the suit that did not have a similar methodology.

132
00:25:44.370 --> 00:25:45.030
Joshua Barton: At the time.

133
00:25:50.520 --> 00:26:00.570
Joshua Barton: So the goal of the capacity planning adjustment or the CPA remains the same as the original workload adjuster, which is to ensure that the programs can maintain an appropriate level of funding for staff.

134
00:26:01.320 --> 00:26:09.390
Joshua Barton: When workload is increasing the CPA provides a mechanism to adjust the resource levels for year to year for industry, driven workload.

135
00:26:10.020 --> 00:26:25.440
Joshua Barton: which helps to mitigate the risk of over or under estimating workload levels, seven years in the future, during the negotiation process, given that timing that negotiations generally start about two years before pre authorization five years of the reauthorization cycle.

136

00:26:27.300 --> 00:26:38.190
Joshua Barton: You know and and so really guessing at the work the levels that far in the futures is not likely to be successful and, like the results either, and over or under resources of these are free programs.

137
00:26:38.760 --> 00:26:50.550
Joshua Barton: So the CPA provides that mechanism provides that mechanism to provide the year over year or annual assessment of resources needed if if any changes are needed.

138
00:26:52.470 --> 00:27:00.420
Joshua Barton: Without the past and plenty adjustment is sustained increase in the industry submissions will result in a risk to the performance on the user fee timelines.

139
00:27:06.210 --> 00:27:16.620
Joshua Barton: So the capacity planning adjustment or CPA is a modernized methodology and are renaming of the legacy pretty full workload adjuster so in many ways it's very similar to the.

140
00:27:17.220 --> 00:27:24.660
Joshua Barton: To the workload adjuster but with some notable modernization and some more sophisticated analytics and better data.

141
00:27:26.040 --> 00:27:33.510
Joshua Barton: there's one output of the overall resource capacity planning capability so there's other analytical outputs that we use to help.

142
00:27:34.980 --> 00:27:41.160
Joshua Barton: Understand resource needs across the Agency but it's the CPA that feeds into the annual fee setting process.

143
00:27:42.930 --> 00:27:45.390
Joshua Barton: CPA is used to just you know fee revenue.

144
00:27:46.890 --> 00:27:58.740
Joshua Barton: yeah the annual fee and revenue amounts as needed for expected workload, it is run once annually has a part of that annual fee and revenue setting process.

145
00:27:59.970 --> 00:28:04.320
Joshua Barton: It is scope to account for changes in direct review workload submitted by the industry.

146
00:28:05.940 --> 00:28:16.470
Joshua Barton: structure to forecast workload changes specific to each Center it's driven by validated submission forecast models and actual time reporting data.

147
00:28:18.030 --> 00:28:29.850
Joshua Barton: And it includes a process of internal checks to ensure that any adjustment to the amounts is is needed, and can realistically be utilized sport needed staff for the forecast to direct review workload.

148
00:28:35.100 --> 00:28:40.170
Joshua Barton: So i'm going to walk through i'm going to step through the methodology, but a couple of key terms, just to kind of define that front.

149
00:28:40.950 --> 00:28:59.130
Joshua Barton: First forecast, which is a practice that predicting future phenomenon, based on the results of previous data, so we use this to forecast industry submissions but it's really important to note that this is based on based in historical data to help inform the future.

150
00:29:01.350 --> 00:29:09.210
Joshua Barton: Also, a full time equivalent or an F T refers to the number of hours expected to be worked by the equivalent of one full time employee.

151
00:29:10.260 --> 00:29:32.520
Joshua Barton: and includes leave and other requirements so when we're assessing the total available hours of an F T music number 22,089 40 hours a week per times to two weeks per year, and if he's not person or a position it's a it's a measure of ours, or a measure of effort.

152
00:29:34.470 --> 00:29:38.880
Joshua Barton: And one other thing to note is that will generally use the.

153
00:29:40.200 --> 00:29:42.750
Joshua Barton: Here, we also have to account for.

154
00:29:44.100 --> 00:29:46.560
Joshua Barton: Other requirements on.

155
00:29:47.850 --> 00:30:02.100

Joshua Barton: On our on our employees, including leave, including professional development, including administrative requirements, so the actual productive time seemed available and empties is less than 28 account for that.

156
00:30:07.560 --> 00:30:18.390
Joshua Barton: So, as noted earlier, the CPA is one mechanism in a setting the no fee revenue amounts, and so this this graphic is a process for setting up.

157
00:30:19.710 --> 00:30:22.740
Joshua Barton: The record revenue amounts each year at least under pity for six.

158
00:30:23.820 --> 00:30:38.490
Joshua Barton: which includes capacity planning adjustment, as noted in the super that CPA place similar similar role in the process, although there are some variations in the overall process and the super to to the fee setting him out.

159
00:30:41.100 --> 00:30:54.630
Joshua Barton: But, so the the capacity planning adjustments one step, instead of the annual revenue amount, and then the annual revenue revenue amount is then divided up, based on formulas prescribing statute to set the specific fee amounts.

160
00:31:02.580 --> 00:31:08.520
Joshua Barton: One thing to note is that the CPA funds become become part of the base revenue for subsequent years.

161
00:31:09.210 --> 00:31:24.300
Joshua Barton: This is necessary to ensure that predictable funding is available to support new staffing, so that we can ensure that if we do hire additional staff get data to pay them in future years, this was a key part of the other negotiated change in price of six.

162
00:31:25.890 --> 00:31:36.960
Joshua Barton: Prior to move the six the workload adjuster funds were not guaranteed to be sustained in future years, which created some uncertainty and meant that FDA had to be conservative and use of the workload adjuster funds.

163
00:31:37.590 --> 00:31:45.690
Joshua Barton: As it could not necessarily count on the funding to be sustainable funding to be sustained for staffing and the future years, so this is a really.

164
00:31:47.520 --> 00:31:53.670
Joshua Barton: really important update in video for six to ensure that predictability of the.

165
00:31:54.720 --> 00:32:01.890
Joshua Barton: funding amounts, so that we can have certainty that we can continue to afford the payroll in future years.

166
00:32:07.980 --> 00:32:13.710
Joshua Barton: Alright, so now, without further ado we'll walk through the capacity planning adjustment process.

167
00:32:15.030 --> 00:32:22.080
Joshua Barton: there's four major steps and i'll give kind of a quick overview and then we'll step through each each step in a little bit more detail.

168
00:32:23.340 --> 00:32:24.870
Joshua Barton: But first we look at.

169
00:32:25.890 --> 00:32:32.970
Joshua Barton: The what is happening on the on the industry side in terms of the volume of submissions.

170
00:32:34.230 --> 00:32:44.100
Joshua Barton: And we dealt develop a set of forecast models that estimate the the volume of industry submissions for the upcoming fiscal year and out years.

171
00:32:44.490 --> 00:32:55.470
Joshua Barton: And, as noted earlier that forecast is based on historical data but looks at leading indicators of likely submissions to help inform the like the workload levels.

172
00:32:59.790 --> 00:33:08.070
Joshua Barton: So, once we have our forecast of industry submissions We then translate that into resource needs in fts in full time equivalents.

173
00:33:08.850 --> 00:33:25.800
Joshua Barton: And that's done with the use of our time reporting data, so we use actual historical time reporting data to understand the amount of effort being invested in each submission type and use the forecasted volume of submissions translate into ftp needs.

174
00:33:31.080 --> 00:33:34.680
Joshua Barton: Then, once we have the output and the forecasted FT he needs.

175
00:33:35.700 --> 00:33:42.000
Joshua Barton: We have a new process new with the the modernized capacity planning adjustment to assess.

176
00:33:44.250 --> 00:33:52.140
Joshua Barton: Other factors to look at the context of operations finances and and other resource data to ensure.

177
00:33:52.830 --> 00:34:10.290
Joshua Barton: That the FDA will be able to utilize any additional funds that are adjusted for during the upcoming fiscal year and then the funds are required sports the additional capacity so then if warranted, if needed, the FDA FTC amounts may be be adjusted.

178
00:34:13.290 --> 00:34:25.320
Joshua Barton: And then, finally, the final feasible adjusted after em out if adjusted is converted into dollars, using the fcs existing F T cost model.

179
00:34:30.990 --> 00:34:35.040
Joshua Barton: So i'll walk in a little bit more detail, we each of these steps here.

180
00:34:37.110 --> 00:34:40.380
Joshua Barton: The first of all, why does a CPA forecast workload.

181
00:34:42.750 --> 00:34:50.520
Joshua Barton: And so we say forecast workload unique forecast the number of industry submissions by type that's included in the capacity planning adjustment.

182
00:34:52.080 --> 00:35:00.060
Joshua Barton: So the number of review staff that are needed are driven by the number of submissions received by the Agency so number of submissions from industry.

183
00:35:01.050 --> 00:35:11.940

Joshua Barton: As noted earlier, but the FDA does not control the volume of industry submissions, but it must review the submissions within the established timeframes, regardless of the volume.

184
00:35:13.110 --> 00:35:30.750
Joshua Barton: Given that it takes time to hire and train review staff, it is important to plan ahead to future expected workload levels to try to maintain adequate staffing levels really so that we can plan to likely level, so we can stay on or ahead of the curve, rather than behind the curve.

185
00:35:36.540 --> 00:35:46.470
Joshua Barton: And the legacy approach with the workload adjuster the workload adjuster used retrospective averages to account for changes in the volume of industry submissions.

186
00:35:48.150 --> 00:35:53.370
Joshua Barton: And that really created a structural gap when workload was increasing.

187
00:35:54.630 --> 00:36:02.760
Joshua Barton: So if you're seeing workload increase and we're using historical averages, and then we need to staff and it takes time to hire and trained.

188
00:36:03.960 --> 00:36:06.840
Joshua Barton: In that increasing workload environment.

189
00:36:08.010 --> 00:36:11.820
Joshua Barton: We were faced with a structural gap are always behind the curve.

190
00:36:13.530 --> 00:36:24.150
Joshua Barton: And so, if the modernization of the capacity planning adjustment and we're using historical data to develop machine learning and other statistical models to predict or forecast volume of industry submissions.

191
00:36:24.810 --> 00:36:30.480
Joshua Barton: Tell better position us to plan to like the workload levels, so we can get get on the curve, instead of always being behind the curve.

192
00:36:36.270 --> 00:36:52.650

Joshua Barton: So how do we forecast workload yeah this this overarching general framework or a process approach, first we identify forecasting objective so say the likely volume of new marketing applications.

193
00:36:53.910 --> 00:37:06.360
Joshua Barton: We do we work to understand the dynamics of what's happening in the industry, what are the available data, what are the underlying trends that drive you know this, this type of submission.

194
00:37:07.710 --> 00:37:10.530
Joshua Barton: And and really understand the drivers of that workload.

195
00:37:12.030 --> 00:37:20.910
Joshua Barton: And three modeling we test different types of machine learning methods or other statistical approaches.

196
00:37:21.930 --> 00:37:36.690
Joshua Barton: To really test the entire suite of approaches to understand what is is is is is the best best approach to work as that type of submission.

197
00:37:38.430 --> 00:37:54.840
Joshua Barton: And then for select we evaluate all of the different models that we've tested and select the model that performs the best over time utilizing a cross validation approach, so this is an approach to ensure the validity of the forecasts and to reduce bias.

198
00:37:56.160 --> 00:38:03.240
Joshua Barton: And this is also tested against historical data so it's important that there is is based on.

199
00:38:04.440 --> 00:38:11.550
Joshua Barton: Some information based on based on the past for this, you know that the type of submission in in question.

200
00:38:13.260 --> 00:38:25.950
Joshua Barton: And then from there, we improve, so we have a consistent cycle or continuously improving each year when we run these models, we look at a problem, a fresh and look at what we've done previously.

201
00:38:26.460 --> 00:38:36.480
Joshua Barton: asked if our assumptions still hold true consider what can be done to improve the models, each year, what other data may be available, how the trends are underlying.

202
00:38:38.010 --> 00:38:51.630
Joshua Barton: Drivers how they shifted if they have and really run through the cycle again for each submission type to ensure that we have the most most realistic and reasonable forecasts available for this process.

203
00:38:57.900 --> 00:39:00.030
Joshua Barton: So what are we forecasting for.

204
00:39:01.050 --> 00:39:17.370
Joshua Barton: The industry submission types that are currently included, so you have to do for here, and the first four lines read them first for just to note were included in the original workload adjuster with some some changes and updates over the years and it sounds some areas.

205
00:39:18.630 --> 00:39:25.950
Joshua Barton: The industry meetings were added by statute and the for the interim capacity planning adjustment, for the first couple of years and then.

206
00:39:26.880 --> 00:39:34.890
Joshua Barton: The label and supplements were included with the the modernization of the capacity planning adjustment, starting with fiscal year 2021 so a lot of good information to have.

207
00:39:36.990 --> 00:39:40.260
Joshua Barton: existed prior to the modernization of capacity planning adjustment.

208
00:39:41.490 --> 00:39:48.570
Joshua Barton: purposes ufa the submission types are very, very similar although tailored to the super Program.

209
00:39:50.490 --> 00:40:06.300
Joshua Barton: And then, of course, assuming reauthorization as negotiated will work also to update the capacity planning adjust adjusters adjustments to reflect new any new requirements, including classically adjustment for can do for.

210
00:40:11.850 --> 00:40:22.020
Joshua Barton: Alright, so our second step, how do we, how do we translate industry submission volumes forecasted industry submission volumes into FT he needs.

211

00:40:24.060 --> 00:40:36.900
Joshua Barton: We we do that, using we quantify that with the estimated time needed per submission, with time reporting existing actual historical time reporting data and historical submission volume.

212
00:40:38.640 --> 00:40:57.870
Joshua Barton: So the sort of illustrative approach outlined here for the most part we're using a somewhat this is slightly simplified but we're really for the most part, using set of averages, based on the number of hours required for submission, which is a term we.

213
00:40:58.890 --> 00:41:07.500
Joshua Barton: term we use, for that is unit effort but it's a lot easier to say human effort than it is to say, average time invested you completed the reveal of one submission.

214
00:41:08.460 --> 00:41:17.970
Joshua Barton: But so In summary, using historical time reporting data to help translate the industry's the forecasted industry submission volume into full time equivalent needs.

215
00:41:25.980 --> 00:41:29.430
Joshua Barton: So the forecasted submission volumes and the unit effort.

216
00:41:30.480 --> 00:41:37.770
Joshua Barton: are combined to form the expected workload, the total expected workload for the scope of work of the classical any adjustment enough to us.

217
00:41:38.820 --> 00:41:40.650
Joshua Barton: So in some we take the submission.

218
00:41:42.060 --> 00:41:46.890
Joshua Barton: The unit effort, which is hours per submission time support casts submissions for each type.

219
00:41:48.120 --> 00:41:52.470
Joshua Barton: Some of those up for a total sum total hours expected to be needed.

220
00:41:53.670 --> 00:42:02.160
Joshua Barton: We then Compare that to current review capacity include an allocation of time to accompany administrative tasks, training and leave as noted earlier.

221
00:42:03.840 --> 00:42:16.560
Joshua Barton: And then, if the if the forecasted F T amp T is needed exceeds the current capacity, we then proceed to the next step, which is to assess the reasonableness of the adjustments.

222
00:42:17.820 --> 00:42:19.380
which was describing the next slide.

223
00:42:23.460 --> 00:42:33.480
Joshua Barton: So, once we have the outputs and the forecasts that he needs, I mean identify if there's a forecasted gap in the FDA means we then go through a structured decision process to review.

224
00:42:34.140 --> 00:42:42.810
Joshua Barton: The review that we refer to this as our managerial adjustment in which we assess operational financial and resourcing data.

225
00:42:44.400 --> 00:42:57.210
Joshua Barton: To ensure that any fee adjustment from the capacity planning adjustment can be utilized to support the direct review workload during the fiscal year and that the funds are required to support that additional review capacity.

226
00:42:59.520 --> 00:43:01.740
Joshua Barton: includes factors such as.

227
00:43:03.750 --> 00:43:13.320
Joshua Barton: How the forecast compared to the prior year actually so we looked at the forecast performance to ensure that that the forecasts are performing reasonably well.

228
00:43:14.700 --> 00:43:33.120
Joshua Barton: We look at whether the forecast change changes are sustained so we look at out your forecasts, and this is how intended to help prevent forecasting to a workload peak or to a valley, we really want to for adjust to sustained workload changes are expected sustained workload changes.

229
00:43:35.280 --> 00:43:42.090
Joshua Barton: We consider hiring an attrition considerations to ensure that any adjustment is reasonably a realistic.

230
00:43:43.740 --> 00:43:46.110
Joshua Barton: to acquire needed fts.

231
00:43:47.130 --> 00:43:55.560
Joshua Barton: To net gain the needed fts and then we look at other financial considerations to ensure that the funding is truly needed to define any additional payroll.

232
00:43:58.140 --> 00:44:12.300
Joshua Barton: These factors are considered and refined each year has more data become available and, as we have more experience with the process, so this is another aspect of our CPA process process which, which we can.

233
00:44:13.470 --> 00:44:15.180
Joshua Barton: continuously improve your over here.

234
00:44:17.460 --> 00:44:24.540
Joshua Barton: And then from there, the final output and fts if any are converted the dollars, using the FDA is F T COs mock.

235
00:44:29.760 --> 00:44:33.000
Joshua Barton: So that's really the process in some.

236
00:44:34.140 --> 00:44:39.180
Joshua Barton: Just to summarize and to kind of circle back to kind of historical context.

237
00:44:40.050 --> 00:44:54.540
Joshua Barton: This table really provides a comparison to the legacy video for workload adjuster and how the modernized capacity plenty of just make compares to that that mechanism, so this is assessed over different features inputs.

238
00:44:56.010 --> 00:45:10.620
Joshua Barton: The inputs, as noted earlier really the capacity planning adjustment uses the same inputs as a workload adjuster, with the exception of the addition of label and supplements and the formal industry meetings which are added her per statute for the interim capacity planning adjustment.

239
00:45:12.420 --> 00:45:27.930
Joshua Barton: To the submission estimation method so that's the workload adjust for us lagging indicators was about historical averages, as mentioned earlier, and the capacity planning adjustment uses leading indicators or forecasts of submissions.

240
00:45:29.340 --> 00:45:38.430
Joshua Barton: Effort estimation method or, in other words, how we convert submissions and to the number of people or staff needed for have to use.

241
00:45:39.450 --> 00:45:46.200
Joshua Barton: The workload adjuster use a convoluted and lagging standard costs methodology to wait submission volume percent changes.

242
00:45:47.610 --> 00:45:56.820
Joshua Barton: Or the capacity planning adjustment uses actual time reporting data so conceptually it's much simpler and using more standardized.

243
00:45:57.990 --> 00:45:58.440
data.

244
00:46:00.210 --> 00:46:09.390
Joshua Barton: internal checks the workload adjuster did not have any process for internal checks, so the output was the output and the reason, Melissa the adjustment was not assessed.

245
00:46:10.440 --> 00:46:22.890
Joshua Barton: That in that managerial adjustment process that I described in the previous slide is a new enhancement to the methodology which helps to serve as an internal check on the reasonableness of the adjustment.

246
00:46:25.170 --> 00:46:42.630
Joshua Barton: The outputs the legacy workload adjuster produced a percentage which was applied to the total revenue amount of the program so the output would be 2% 3% and that two or 3% or whatever it was would be applied to the total annual revenue amount.

247
00:46:44.430 --> 00:46:59.850
Joshua Barton: The output for the capacity plenty adjustment are measured in full time equivalents and needed and then convert convert into dollar amounts by a standard cost model, so perhaps a bit more interpreted in terms of life and what is being adjusted for.

248
00:47:02.100 --> 00:47:09.330
Joshua Barton: And then the the last feature, this is standing on the just of the adjustment, as noted earlier, the legacy workload adjuster.

249

00:47:10.350 --> 00:47:16.170
Joshua Barton: The adjustment funds were not guaranteed in future years mean there's no guarantee that the payroll could be sustained.

250
00:47:17.160 --> 00:47:32.190
Joshua Barton: And with the negotiated updates within the current authorization period that was changed so that the adjustment funds would be part of the base revenue to ensure that payroll can be sustained moving forward.

251
00:47:38.760 --> 00:47:50.580
Joshua Barton: CPA next steps we will continue your every year to refine and improve all aspects of the past company adjustment process with with additional data.

252
00:47:51.540 --> 00:48:05.220
Joshua Barton: and refinement of our of our of our processes and then implement any new requirements, assuming reauthorization including a capacity planning adjustment, for it can do.

253
00:48:09.840 --> 00:48:28.710
Joshua Barton: And I believe that's my last slide so I just again want to thank everyone for attending today and thank everyone who's contributed in this in the FDA and to to help him to get us to this point, calm and with that i'll turn this to any cash to give a little bit of a recap on RC.

254
00:48:37.710 --> 00:48:38.670
Andrew Kish: creates great thanks josh.

255
00:48:39.840 --> 00:48:45.240
Andrew Kish: No, that was a lot of information so hope everyone is able to digest it just going to.

256
00:48:46.740 --> 00:48:58.320
Andrew Kish: Give a quick summary of some of the key points really in a question and answer format, in case you've come across these questions are these questions are in your mind right now, after that presentation just want to really.

257
00:48:59.940 --> 00:49:05.760
Andrew Kish: emphasize a few things around the resource capacity planning so i'll just run through these.

258
00:49:06.780 --> 00:49:15.300

Andrew Kish: So again, why does, why does a particular program have a capacity planning adjustment and as josh mentioned, this is really a mechanism to adjust our annual type.

259
00:49:15.780 --> 00:49:24.360
Andrew Kish: target revenue to count for sustained increases and workload then ensure that FDA is resource to continue meeting our performance commitments.

260
00:49:25.170 --> 00:49:32.430
Andrew Kish: Without this adjustment, we would be unable to keep up with increases in industry, driven workload in the program and would fall behind it, our performance.

261
00:49:34.740 --> 00:49:36.870
Andrew Kish: Is this a new concept capacity planning.

262
00:49:37.890 --> 00:49:46.320
Andrew Kish: Particularly the capacity planning adjustment no it's not a new concept, the precursor to the capacity planning adjustment was the proof of workload adjuster josh mentioned that came online.

263
00:49:46.740 --> 00:49:56.580
Andrew Kish: To do for three capacity planning adjustment is is really the modernized old workload adjuster methodology with advanced analytics and modernize time reporting.

264
00:49:59.550 --> 00:50:07.890
Andrew Kish: Mike might be wondering is resource capacity planning intended to limit or greatly expand the growth of the producer program, the answer is no, to both of those.

265
00:50:08.430 --> 00:50:20.880
Andrew Kish: Other resource capacity planning function is a data driven approach to accurately assess changes and resourcing capacity needs of the proof of program and those changes are driven by industry activity primarily.

266
00:50:21.960 --> 00:50:23.820
Andrew Kish: So FDA follows the data here.

267
00:50:25.680 --> 00:50:27.030
Andrew Kish: And next slide.

268

00:50:28.290 --> 00:50:38.220
Andrew Kish: So yeah, what are the main drivers of capacity planning adjustment just quick recap of those really two inputs industry activity, the volume of industry submissions and formal meetings in the Program.

269
00:50:38.910 --> 00:50:47.310
Andrew Kish: So formal meetings scheduled written response only number of submissions that come in, have mbas and delays commercial ids with activity and supplements.

270
00:50:48.690 --> 00:50:54.810
Andrew Kish: Other input is modernized time reporting this This allows this reflects how much effort it takes to complete that work.

271
00:50:58.590 --> 00:51:10.260
Andrew Kish: might be wondering can FDA increase the capacity adjustment to whatever it wants to answer is no, we cannot FDA follows the analytical output from the capacity planning methodology, which has been reviewed and validated by external parties.

272
00:51:11.550 --> 00:51:22.110
Andrew Kish: And also something that's new in this capacity planning compared to the old workload adjuster is the manager adjustment structure decision process really to ensure reasonable and realistic adjustments.

273
00:51:23.010 --> 00:51:33.000
Andrew Kish: And if you look back at our past couple of hours FDA has decreased the adjustment from the forecasted resource need via the manager adjustment step in the past two fiscal years.

274
00:51:36.360 --> 00:51:52.350
Andrew Kish: So that was another one does FDA have a way to do a reality check on the feasibility of acquiring new resources as part of this capacity planning adjustment, the answer is yes FDA included and manual in a journal adjustment and the new CPA methodology as an internal control.

275
00:51:53.700 --> 00:51:59.280
Andrew Kish: What happens in this step is we assess the operational financial and resourcing data to ensure that any fee adjustment.

276
00:51:59.640 --> 00:52:05.790
Andrew Kish: From the CPA can be utilized to support that direct review workload during that that fiscal year of adjustment.

277

00:52:06.600 --> 00:52:15.600
Andrew Kish: So this includes a realistic assessment of hiring attrition in the program and looking for efficiencies optimize the program so if we see our.

278
00:52:16.110 --> 00:52:20.430
Andrew Kish: Our hiring might be a bit challenging and attrition is high, we would not at.

279
00:52:21.090 --> 00:52:35.010
Andrew Kish: An our resource estimate is is beyond what we believe we can actually bring on that year, we would not take those additional resources, reflecting on the reality of fact, we might be wouldn't be able to bring on those resources new staff during that time frame.

280
00:52:37.620 --> 00:52:49.290
Andrew Kish: So some key takeaways and a lot of information, but some key takeaways on capacity planning and capacity planning adjustment and that's all I have Monica alternative review to wrap up the meeting.

281
00:52:54.510 --> 00:53:01.560
Monica.Ellerbe@fda.hhs.gov: Thank you, my day and thank you all for your attendance today so close up the meeting I have a few final pieces of information to provide.

282
00:53:02.100 --> 00:53:10.980
Monica.Ellerbe@fda.hhs.gov: In accordance with the Federal registry notice, we are now entering the open public comment portion of the meeting, where individuals will have the opportunity to provide comments to the FDA.

283
00:53:11.520 --> 00:53:23.310
Monica.Ellerbe@fda.hhs.gov: there's also a public docket open till July, the seventh to which publix to which the public can submit comments to submit a public comment, please visit regulations that the US docket number FDA.

284
00:53:24.390 --> 00:53:39.540
Monica.Ellerbe@fda.hhs.gov: N, as in Nancy 1875 to locate this meeting and submit your comment, if you would like to access materials from today's meeting they can be found this public meetings web page at FDA gov and thank you all for listening and attending today's meeting.