From: Tierney, Julia
To: Marks, Peter
Cc: Walinsky, Sarah
Subject: RE: Catching up
Date: Monday, July 19, 2021 9:09:00 PM

Happy to chat. I spoke with Janet tonight and she is aware.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, July 19, 2021 6:18 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>
Subject: FW: Catching up

Dear Julie and Sarah

Thoughts welcome. May be easiest to touch bases by phone. Thanks.

Best Regards,

Peter

From: Marks, Peter
Sent: Monday, July 19, 2021 6:16 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: Catching up

Dear Marion,

Thanks for all of these questions, all of which are entirely reasonable. I have been giving them some thought and have some thoughts to share with you, for which I would welcome your feedback. Look forward to speaking in the morning.

Best Regards,

Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Monday, July 19, 2021 6:14 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Catching up

Dear Peter,

I informed DVRPA and DVP management that for the time that I will be (b) (6), JW assigned you direct oversight of the Pfizer Corminaty BLA and that Phil will be overseeing other regulatory files. DVRPA and DVP management requested, before they inform their staff, to get clarification on the process that will be followed, specifically:

- How will you be interacting with the review team, i.e., will you be present at all their meetings, will you be directly interacting with the Chair?
- JW mentioned she wants to be briefed on the review process, what would this look like?
- I typically get updates from DVP and DVRPA and also interact with OBE: How do you foresee such interaction?
- Will you be directly interacting with Theresa Finn and Karen Farizo regarding labeling, PerC and getting agreement on potential PMRs?
- Have OBE and OCBQ be informed?

As you can imagine, there is a great deal of Angst and uncertainty and I would appreciate if we can discuss the above in our meeting tomorrow. I need to provide reassurance to the team. Also, it is not clear to me whether I, and for that matter Phil, will be put back in charge

regarding this BLA once I return (b) (6) .
Thank you,
Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, July 19, 2021 11:32 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: Catching up

Dear Marion,

Just wanted to follow up on this morning's meeting with Janet. I appreciate all of the work that you and OVRR have done here and want to try to connect tomorrow to make sure that a number of different issues that are pending. I am open from 7 to 7:30 or 8 to 9. Just let me know what might work for you. Also, thanks very much for attending the (b) (4) meeting this afternoon. Though I may spend more than the hour with them, I will let them know that some team members will need to leave after and hour. Thanks again for doing this.

Best Regards,
Peter

From: Sheehy, Janice
To: Tierney, Julia
Subject: RE: Meeting w CBER
Date: Friday, July 16, 2021 3:06:55 PM

Yes, will do, thanks. -j

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, July 16, 2021 3:06 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Meeting w CBER
Thanks. And assume meeting will not be forwardable. Thanks.

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Friday, July 16, 2021 3:05 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: Meeting w CBER
FYI

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, July 16, 2021 3:04 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>; Grantham, Gloria <Gloria.Grantham@fda.hhs.gov>
Cc: Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Meeting w CBER
Dear Janice,
Please just invite Marion Gruber and me.
Best Regards,
Peter

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Friday, July 16, 2021 3:02 PM
To: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>; Grantham, Gloria <Gloria.Grantham@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Meeting w CBER
Hi, just checking back in please for the names of the CBER folks to be included in Monday's 8:30am.
Thanks so much! -janice

From: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
Sent: Tuesday, July 13, 2021 7:45 AM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>
Subject: RE: Meeting w CBER
Good Morning Janice,
The best time for Dr. Marks would be:
Monday, July 19: 8:30-9:00am
Sincerely,
Charlene

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Tuesday, July 13, 2021 7:13 AM
To: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>
Subject: FW: Meeting w CBER

Good morning, Charlene!

Per Julie's email below, would you please let me know which date/time (30-minute block) works best for Dr. Marks:

Friday, July 16: 2:00-3:00pm, 4:00-5:00pm

Monday, July 19: 8:30-9:00am, 9:30-10:00am

I will wait to hear who Dr. Marks would like to have included on the calendar invite.

Thank you!

-janice

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, July 12, 2021 9:06 PM
To: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: Meeting w CBER

Can you please find 30 minutes on Friday 7/16 afternoon or Monday 7/19 morning for JW to meet w Peter Marks and others in CBER to discuss vaccine review? For now, let's just hold on JW, mine, and Peter's calendars and then Peter can tell us who he'd like to invite from his staff.

From: Marks, Peter
To: Woodcock, Janet; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timeline
Date: Friday, July 16, 2021 11:20:48 AM
Attachments: image001.png

Dear Janet,
Thanks. In my mind, the issue is that for four weeks, aside from mandatory IND review and safety work and continuing work on one PDUFA goal vaccine, all available hands in the office of vaccines, epi and my immediate office should be working to get the Pfizer vaccine done. I am putting together a notional Gantt chart that I will refine.
I am committed to getting this done timely – we will make it happen.
(I have Warp Speed to live up to!)
Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, July 16, 2021 11:10 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine BLA review timeline
Well they seem open to additional support on other vaccine efforts, and are already working with CDER office of computational science, which is a good thing. Peter you can find out more when you take over. jw

---

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, July 16, 2021 9:26 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Just reupping

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, July 15, 2021 10:11 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Dear Janet,
Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the Sept 15 date.
Thanks very much.
Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>

Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>

Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,

Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.

Marion

Marion F. Gruber, Ph.D

Director

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Silver Spring, Maryland 20993

Tel.: (301) 796 1856

Email: marion.gruber@fda.hhs.gov

From: Woodcock, Janet
To: Marks, Peter; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timeline
Date: Thursday, July 15, 2021 10:12:49 AM
Attachments: image001.png

Sure we can set up some time. jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, July 15, 2021 10:11 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline

Dear Janet,

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Thanks very much.

Best Regards,

Peter

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Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Pfizer COVID-19 vaccine BLA review timeline

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Silver Spring, Maryland 20993
Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov

From: Woodcock, Janet
To: Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Date: Saturday, July 17, 2021 1:07:11 PM
Attachments: image001.png

Great, thanks. jw

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Saturday, July 17, 2021 12:45 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Re: Pfizer COVID-19 vaccine BLA review timelines
Sent an invite for 2

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Saturday, July 17, 2021 12:01:37 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Agree. Anytime before 5 is good. wj

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Saturday, July 17, 2021 11:56 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Dear Janet,
Totally fine with whatever you want to do with this. Based on what Marion provided, I think that shaving three weeks off is truly possible. We just need to motivate the team around this cause – that is something I actually know how to do as a leader (a la the beginning of Warp Speed and my previous work in industry).
I could do this afternoon anytime after 2 PM. Also could probably make 1 pm tomorrow work.
Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Saturday, July 17, 2021 11:52 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
This afternoon or tomorrow is good for me. Marion has asked to include Phil Krause in the meeting with me. jw

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, July 16, 2021 6:56 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Happy to put a call-in on over the weekend for us whenever works best for the two of you.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, July 16, 2021 6:08 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: Pfizer COVID-19 vaccine BLA review timelines

Dear Janet and Julie,
Please see the attached. Marion finally provided this timeline. I can already see a number of potential efficiencies. Perhaps we can discuss over the weekend briefly in preparation for Monday?
Thanks.
Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, July 16, 2021 5:39 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Pfizer COVID-19 vaccine BLA review timelines

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Marion
[I saw earlier today that CNN announced that this review will be completed within 2 months; thus, Sep 15, even though ambitious, is within this projected timeline.]

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From: Woodcock, Janet
To: Marks, Peter; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Date: Saturday, July 17, 2021 12:01:39 PM
Attachments: image001.png

Agree. Anytime before 5 is good. wj

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From: Woodcock, Janet
To: Marks, Peter; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Date: Saturday, July 17, 2021 11:53:05 AM
Attachments: image001.png

Tomorrow 1 or 2 PM? jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, July 16, 2021 7:19 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines

Dear Julie,

Pretty much any time that can work for Janet could work for me this weekend.

Best Regards,

Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, July 16, 2021 6:56 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
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Date: Saturday, July 17, 2021 11:52:01 AM
Attachments: image001.png

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Email: marion.gruber@fda.hhs.gov

From: Marks, Peter
To: Woodcock, Janet
Cc: Tierney, Julia
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Date: Thursday, July 15, 2021 10:11:27 AM
Attachments: image001.png
Pfizer COVID-19 vaccine BLA review timeline.docx

Dear Janet,

Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the Sept 15 date.

Thanks very much.

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Peter

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Pfizer COVID-19 STN 125742.0 BLA target AD: 09/15/2021

OVRR's decision to expedite the planned completion of the Pfizer BLA review to September 15, 2021, was based on a careful consideration of the steps that need to take place. OVRR's logic is outlined below.

The Pfizer BLA is a complex BLA

Of note, the pivotal study supporting the BLA was conducted in over 40,000 subjects. To provide additional assurance of the safety and effectiveness of this product that is currently administered to millions of subjects in the US and globally, we requested 6 months safety follow-up to support the BLA as opposed to the 2 months safety follow-up that supported the EUA. The applicant has also submitted additional efficacy data on substantial numbers of cases in vaccine and control groups that were not available with the EUA request submission and data on post-authorization safety experience. These additional data are substantial and enable additional important analyses.

The BLA merits a complete and thorough review

OVRR's reviews of vaccine BLAs, unlike those of regulators in other countries, do not rely on summary tables that are generated by the developer. OVRR views it as essential that review of the safety and efficacy data not only includes an evaluation of the data analyses conducted by the applicant, but also includes CBER's own analysis of the datasets submitted by Pfizer. This has been OVRR's standard for all other BLAs, and while time-consuming, OVRR believes that confidence in COVID vaccines would not be served by starting to cut corners on this review.

While the efficacy data may appear simple to evaluate, longer term follow-up of placebo-controlled data provides essential information that may be of high relevance to discussions about boosting. Moreover, the safety data represent the only placebo-controlled data we have on the safety of this vaccine. These placebo-controlled data are likely to be free of biases that might occur in post-licensure observational studies, so it is imperative to carefully review the reported adverse events, including evaluation of the sponsor's attribution of these events (or lack thereof) to vaccination.

As compared with other BLAs, the proposed completion date of Sept 15 would be unprecedented

The Pfizer COVID-19 BLA received priority designation, allowing 8 months for CBER review and is a "rolling" BLA. Note that the final piece of the roll was received on May 18, 2021 at which point the review clock started. We are targeting September 15, 2021 as the date we will be taking regulatory action, which is less than 4 months from the date the last section of the BLA was submitted. Thus, we will be reviewing this very large and complex BLA in a 1/3 rd of the time typically allowed for a BLA standard application and in less than half the time allocated for a priority review application.

This is possible only with deprioritization of other reviews, including some related to COVID, and reassignment of work to other experienced medical officers.

At this time, while we have hired additional medical officers, we have a limited number of clinical reviewers with the specialized experience needed to assess complex preventive vaccine files requiring comprehensive review, such as those for COVID vaccines that have progressed to pursuing an EUA or BLA. Addressing the high volume of COVID-related work has necessitated deprioritizing some vaccine files.

In addition, we have de-prioritized certain COVID-vaccine related submissions (including some from Pfizer), e.g., amendments pertaining to protocols and studies in pregnant women and immunocompromised subjects, until such time that the BLA review is completed.

However, Pfizer requested advice on 4 booster protocols and advice on the safety data base to support use of the COVID-19 vaccine in pediatric populations 6 months – 12 years of age. These cannot be deprioritized and will need to be reviewed by staff and overseen by supervisors familiar with the Pfizer COVID vaccine IND ad EUA, concurrent with review activities for the Pfizer COVID-19 BLA.

While it was not possible to completely reassign other COVID-19 vaccine- related and non-COVID vaccine-related review work for the MOs assigned to the Pfizer BLA, workload adjustments have been made to allow them to focus nearly exclusively on review of this BLA.

In addition, if the trajectory of the pandemic/emergence of variant of concerns (i.e., delta variant) necessitates the review of EUA amendments for booster doses for the currently U.S. EUA authorized COVID-19 vaccines, from a public health perspective, these reviews will need to take priority over completing the BLA review by September 15, 2021.

Additional support from outside OVRR will not speed up the review

Review efforts for the Pfizer COVID-19 vaccine BLA in the various disciplines, including CMC, nonclinical, PV and facility is ongoing. Information requests have been sent to Pfizer as part of these reviews, and responses are pending. However, the rate-limiting step in regard to potentially accelerating the review timeline to earlier than September 15 is the clinical review, considering the complexity of the clinical safety and effectiveness data. The safety review encompasses a critical evaluation and interpretation of solicited and unsolicited safety data and SAES, and clinical AEs of interest including, but not limited to, the myocarditis signal that has been observed following the administration of the Pfizer COVID-19 vaccine under EUA. We are also performing subgroup analyses of safety and effectiveness data for race, ethnicity and subjects with underlying conditions. Completion of these reviews may require additional correspondence with the sponsor. We hope that reviewers will be able to complete their detailed review memos for the various review activities by the beginning of September as planned. After this has been finished, there are important additional review activities to be completed, including label

negotiations, supervisory review, SBRA preparation, etc. such that it would not be possible to issue the license until September 15.

The experienced MOs assigned to this file are working closely with the data analytics team in CDER-OCS and staff in CBER/OBE who are supporting their review efforts. The need for coordination of evaluation and consistency within the review would lead to diminishing returns if additional staff would be added to this effort. In addition, the reviews have already been initiated and sections of the review are being written as they are completed. Other sections depend on the reviews of the earlier sections, so those parts of the review cannot be completed until the earlier parts of the review have been done, and because they need to take the subtleties of the earlier parts into account, cannot as reliably be performed by medical officers who are new to the file. Thus, assigning additional MOs (even if experienced) to assist in review of the Pfizer COVID vaccine BLA, it is likely that the review effort would be will delayed rather than expedited the review effort as these reassigned individuals would need to familiarize themselves with the file.

Furthermore, reassignment of experienced medical officers to the Pfizer BLA would lead to a cascade of further reassignments and their own assignments will be delayed ultimately leading to an increase in back-log including critical ongoing review activities to support:

- Many anticipated several BLA submissions in in 3/4Q of 2021 including the BLAs for the (b) (4) (b) (4) and BLAs for (b) (4) (b) (4) all of which are likely to qualify for priority review designation
- The (b) (4) BLA,
- Several BLA supplements including an efficacy supplement for (b) (4) for the pediatric population,
- Efficacy supplements for (b) (4) and
- Booster protocols for the Pfizer, Moderna, and Janssen COVID EUAs.

In summary, it is not possible to further abbreviate the BLA review timeline for the Pfizer COVID-19 vaccine BLA, our target review date for this file remains September 15, 2021.

Additional support from outside OVRR, if effectively used, might reduce the need to deprioritize certain submissions.

Going forward, OVRR will continue to assign lower priority INDs (including COVID vaccines submitted by small entities and academic investigators) to less experienced staff. Some may need to be deprioritized in order to allow our most experienced reviewers to focus on the submissions that have the greatest public health importance.

In addition, to be able to cope with its heavy and steadily increasing regulatory workload, the following is suggested:

- Hiring or assigning review staff from other offices/centers to support review activities regarding lower priority non-COVID files (e.g., (b) (4)) so that staff familiar with the COVID -19 vaccine files can continue to focus their review activities on these submissions,
- For CBER to hire additional program analysts to perform data analytics to support MO review activities
- Extension of the J review contract by one year
- For CBER to provide adequate IT support to its staff. It has been our experience that staff who need their laptops refreshed are receiving sub-standard equipment, i.e., refurbished computers that present with multiple problems. As a consequence of this being an Agency-wide issue, ERIC is backed up and cannot provide timely support. This has caused delays in the completion of review assignments.

From: Marks, Peter
To: Hussey, Deirdre
Cc: Walinsky, Sarah
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Date: Friday, July 16, 2021 9:48:15 AM
Attachments: image001.png
Pfizer COVID-19 vaccine BLA review timeline.docx
Review timeline.msg

Dear Deirdre,

I am copying this to you because I think that it is important to document that despite repeated verbal attempts, and as documented in the attached email, I have asked Marion for a timeline that would help justify the September 15 data that she provides for completion of the review.

To further expedite the Pfizer BLA review, during the past month I have also repeatedly offered Marion additional resources from the center and my immediate office, some of whom have deep experience in vaccines. However, she had declined, stating that this would not help.

When asked how many clinical reviewers are working on the file, Marion has told me that there are two, and I have questioned why more could not be placed on the file to assist, but she states that does not feel that this would help.

Yesterday, 7/15, with Celia on the line, I reminded Marion that I asked for a timeline of activities, and she said that she would speak to the review team the evening of 7/15 and get back to me. However, she also noted that she didn't believe that the timelines would change.

In my opinion, the recurrent recent deterioration during the current public health emergency necessitates that we fully mobilize all center resources in order to approve a BLA for a COVID-19 vaccine as rapidly as possible.

I am hoping that Marion will get back to me soon with a timeline that we can discuss.

Best Regards,

Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,

Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.

Marion

Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993
Tel.: (301) 796 1856

Email: marion.gruber@fda.hhs.gov

From: Marks, Peter
To: Gruber, Marion
Cc: Walinsky, Sarah
Subject: Review timeline
Date: Thursday, July 8, 2021 12:51:00 PM

Dear Marion,

Thanks so much for the update on the timelines this morning. Regarding the Pfizer review timeline, by early next week would it be possible to get a high level listing of review activities sorted by week over the course of the next two and a half months. I need to be able to demonstrate to Janet that we are diligently pursuing the process, and this would be very helpful. The level of detail would not need to be very great – just key completion milestones such as "completion of clinical review," "completion of labeling negotiation," etc.

Best Regards,

Peter

From: Marks, Peter
To: Tierney, Julia
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Date: Thursday, July 15, 2021 8:23:15 AM
Attachments: image001.png
Pfizer COVID-19 vaccine BLA review timeline.docx

Dear Julie,

Let's discuss this morning before I forward this to Janet later. Thanks.

Best Regards,

Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>

Sent: Thursday, July 15, 2021 8:00 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>

Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>

Subject: Pfizer COVID-19 vaccine BLA review timeline

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Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993
Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov

From:	Marks, Peter
To:	Woodcock, Janet; Tierney, Julia
Subject:	FW: Pfizer COVID-19 vaccine BLA review timelines
Date:	Friday, July 16, 2021 6:08:12 PM
Attachments:	Updated Pfizer COVID Approval Timeline.pptx image001.png

Dear Janet and Julie,

Please see the attached. Marion finally provided this timeline. I can already see a number of potential efficiencies. Perhaps we can discuss over the weekend briefly in preparation for Monday?

Thanks.

Best Regards,

Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>

Sent: Friday, July 16, 2021 5:39 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>

Subject: Pfizer COVID-19 vaccine BLA review timelines

Dear Peter,

As requested, see attached our projected timelines for completing currently ongoing reviews, tasks and responsibilities for the above BLA. Of note, the bar graphs reflect targeted completion dates, some of these pending timely sponsor response to information request which we have been and are sending as we review the info contained in the submission. The target ADD is September 15. Note that DBSQC DS and DP testing will not be completed at that time because of reagent shortage.

Marion

[I saw earlier today that CNN announced that this review will be completed within 2 months; thus, Sep 15, even though ambitious, is within this projected timeline.]

Marion F. Gruber, Ph.D

Director

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

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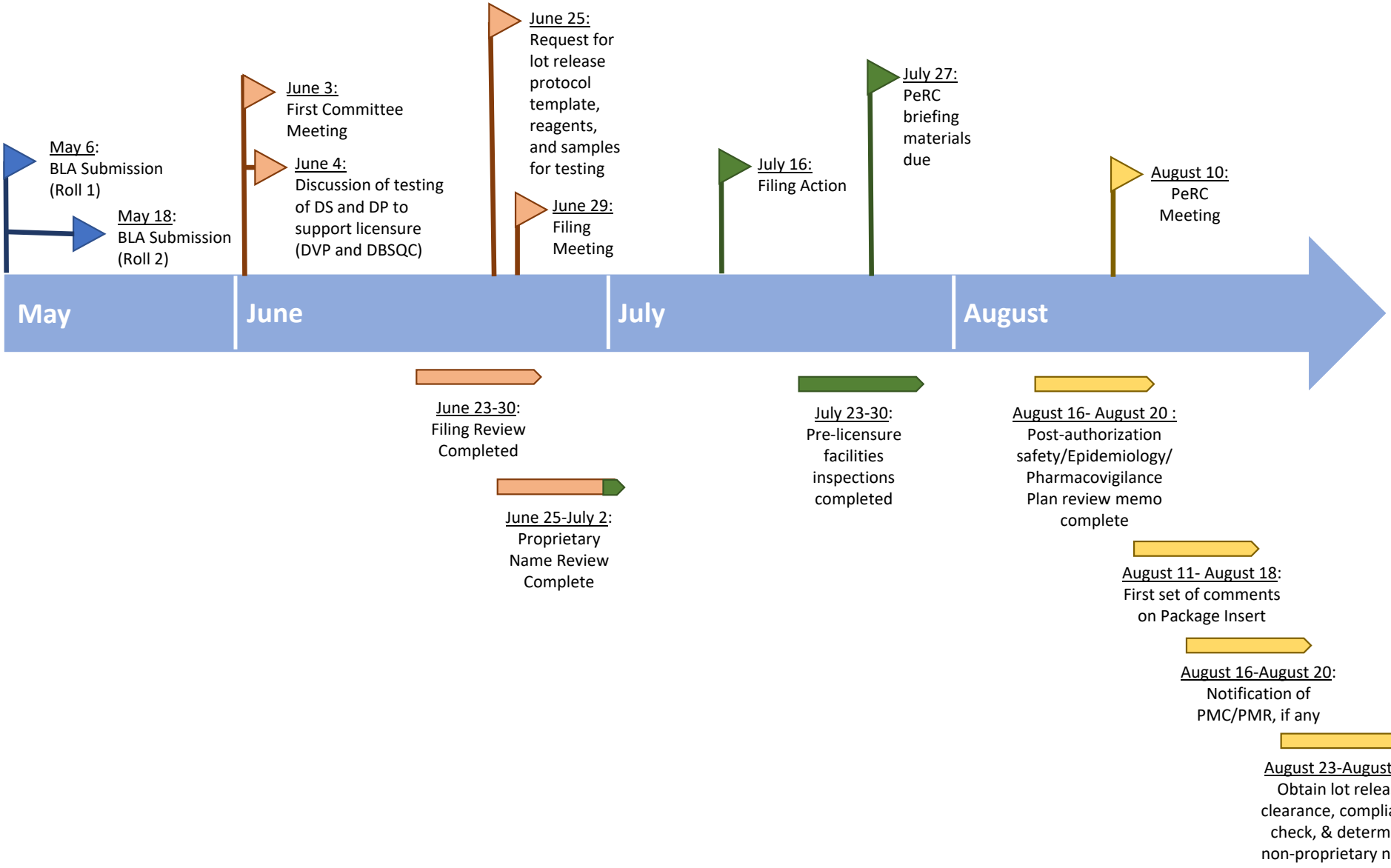
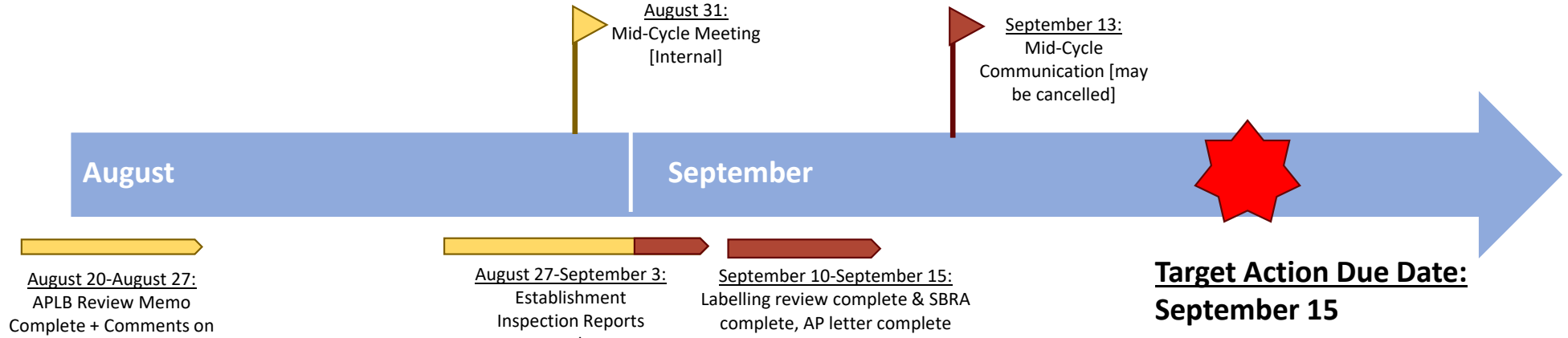
Silver Spring, Maryland 20993

Tel.: (301) 796 1856

Email: marion.gruber@fda.hhs.gov





***Pending timely sponsor response to info requests

From:	Sheehy, Janice
To:	Tierney, Julia; Woodcock, Janet
Subject:	RE: Vaccine Review
Date:	Saturday, July 17, 2021 4:37:50 PM

Will do, thanks! -j

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Saturday, July 17, 2021 2:28 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine Review
Janice – I spoke with Janet, please extend the invitation to Phil Krause.
Thanks,
Julie

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Saturday, July 17, 2021 12:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Vaccine Review
Thank you, will do.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Saturday, July 17, 2021 11:51 AM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Vaccine Review
Hold off on responding. jw

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Friday, July 16, 2021 6:58 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Vaccine Review
Hi, please see Marion's email below. Thanks! -j
-----Original Appointment-----
From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, July 16, 2021 6:45 PM
To: Sheehy, Janice; Olivarria, Frank; Goldie, Christina; Copeland, Jakea
Subject: Accepted: Vaccine Review
When: Monday, July 19, 2021 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Please see Zoom below
Dear Janet,
Thanks for the invitation. Would it be possible to extent this invitation to my deputy, Dr. Philip Krause ?
Marion

From: Sheehy, Janice
To: Tierney, Julia
Subject: RE: Vaccine Review
Date: Friday, July 16, 2021 7:08:38 PM

Ok thank you.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, July 16, 2021 7:00 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Vaccine Review

I'm going to defer to JW on this.

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Friday, July 16, 2021 6:58 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Vaccine Review

Hi, please see Marion's email below. Thanks! -j

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