

From: [Krause, Philip](#)
To: [Finn, Theresa](#)
Cc: [Pratt, Douglas R.](#)
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research
Date: Wednesday, August 4, 2021 12:04:00 PM

I will bring it up this afternoon as an option that may require more discussion.

From: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 12:01 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Cc: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Phil – I have meetings 12:30-2:30 and then from 3-5. We have a bunch of these queries but we are in a bind – (b) (5)

[REDACTED]
[REDACTED]. Thus, an IND is required.

Maybe we can get a verbal OK from (b) (5).

Theresa

From: Krause, Philip <[Philip.Krause@fda.hhs.gov](#)>
Sent: Wednesday, August 4, 2021 10:35 AM
To: Finn, Theresa <[Theresa.Finn@fda.hhs.gov](#)>
Cc: Pratt, Douglas R. <[Douglas.Pratt@fda.hhs.gov](#)>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

But it doesn't sound like they actually want to do a study. They just want to vaccinate these people— if I am reading this correctly. The CDC EA IND (b) (5)

I don't know if OCC (b) (5)

So I think (b) (5)

I am on a call with Peter Marks and Amanda Cohen at CDC at 230, but have nonstop meetings

Hi Phil,

[illegible]

Understandably, the PI is getting impatient. I suppose (b) (5)
 (b) (5) – but we are so slammed right now (b) (5)
 (b) (5)

Theresa

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:07 AM
To: Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

Any word on how to respond to these folks?

From: (b) (4)
Sent: Wednesday, August 4, 2021 9:43 AM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; (b) (4)
(b) (4); McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy
<Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; (b) (4)
(b) (4)
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Gemignani,

We currently have a few immune compromised patients in our ICU who were fully vaccinated. It is difficult to remain patient when we are on the front lines observing this happen. We would like to initiate a third dose boost as soon as possible on our most vulnerable patients.

Is there a way to expedite this request?

Appreciatively,

(b) (4)

(b) (4)

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Wednesday, July 28, 2021 4:51 PM
To: (b) (4)
(b) (4); McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy
<Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Good afternoon (b) (4)

Thank you for your patience. We will respond to you and (b) (4) as soon as we have a final determination from CBER.

Kind regards,
Helen Gemignani

From: (b) (4)
Sent: Wednesday, July 28, 2021 3:22 PM
To: (b) (4) Gemignani, Helen S
<Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4); Nelle, Timothy
<Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

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Dear Dr. Gemignani,

Please provide any updates on consideration of our study.

Appreciatively,

(b) (4)

(b) (4)

From: (b) (4)
Sent: Monday, July 26, 2021 12:19 PM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris
<Loris.McVittie@fda.hhs.gov>
Cc: (b) (4)
(b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R.
<Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

Thank you for confirming receipt of our materials. Please provide a status update and let us know if any additional information is needed.

Thanks,

(b) (4)

(b) (4)

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>

Sent: Tuesday, July 20, 2021 11:09 AM

To: (b) (4) McVittie, Loris <Loris.McVittie@fda.hhs.gov>

Cc: (b) (4)

(b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>

Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Thank you (b) (4). I confirm receipt of your supportive documentation attachment within your 16 July email.

We hope to respond to you within this week.

Helen

From: (b) (4)

Sent: Friday, July 16, 2021 12:39 PM

To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>

Cc: (b) (4)

(b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>

Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Drs. Gemignani and McVittie,

Per Dr. Nelle's out of office message, I am forwarding the following informal IND exemption determination request to you.

Please confirm receipt and let us know when we can anticipate hearing your determination.

Thanks,

(b) (4)

Dear Dr. Nelle,

On behalf of (b) (4), attached please find a description of her intended study. We are submitting to you for an informal determination of whether the IND exemption regulations (21 CFR 312.2(b)) apply per Ms. Kallungal's recommendation, below. We have included a description of the study with a clearly identified study population and a discussion of the issues from our perspective.

Please confirm receipt and let us know when we can anticipate hearing your determination.

Thanks,

(b) (4)

(b) (4)

From: Kallungal, Beatrice <Beatrice.Kallungal@fda.hhs.gov>

Sent: Tuesday, July 13, 2021 12:55 PM

To: (b) (4)

Cc: Kallungal, Beatrice <Beatrice.Kallungal@fda.hhs.gov>

Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Dear (b) (4)

The Office of Vaccines Research and Review (OVRR), CBER has provided the following responses to your questions:

1. Are there any restrictions on the EUA Covid-19 vaccines that preclude their use in research (e.g. a study of heterologous vaccine boost doses)?

Response: COVID-19 vaccines authorized for emergency use may be studied in clinical investigations.

2. Are the EUA vaccines considered “lawfully marketed” (21 CFR 312.2(b)) for the purposes of an IND exemption (though we anticipate it is likely that we would still file an IND based on other criteria)?

Response: Vaccines which are available under EUA may be considered “lawfully marketed” if used under the scope of authorization as described in the Letter of Authorization (LOA) for each product. If the product you intend to use in your clinical investigation is sourced from the US government for administration by vaccination providers, as described in the LOA, and the proposed use is to prevent COVID-19 in the age group for which the product is authorized, a proposed study may be considered for IND exemption under 21.CFR312.2(b), which pertains to lawfully marketed products.

You may wish to submit a brief description of your intended study for an informal determination of whether the IND exemption regulations of 21CFR312.2(b) may apply. Note that an important consideration is the possible risk to subjects so please clearly identify the intended study population and include a discussion of the issue from your perspective. You may submit this information via email to the Chief of the Review Management Support Branch in the Office of Vaccines Research and Review, Dr. Tim Nelle: Timothy.Nelle@fda.hhs.gov.

3. Assuming an IND is required, would the FDA require that CMC data (or a Letter of Authorization from the manufacturer) be submitted with the IND application (or are the EUA materials sufficient to address this)?

Response: Use under IND requires the submission of CMC information. This may be provided through a letter of authorization from the manufacturer. If the proposed investigation will use authorized vaccine and a LOA cannot be provided the IND sponsor can request a waiver of the requirement for CMC information as described in 21 CFR 312.10.

If you have any further questions regarding the use of authorized COVID-19 vaccines please contact the Office of Communications, Outreach and

Development via email at Industry.Biologics@fda.hhs.gov, 240-402-8010, or 800-835-4709.

Regards,

Beatrice Kallungal, MS
Branch Chief
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation Research
U.S. Food and Drug Administration
Tel: 301 796 9304
Cell: 240 620 7733

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