



December 27, 2022

Via Email: [lburke@judicialwatch.org](mailto:lburke@judicialwatch.org)

Lauren Burke  
Judicial Watch, Inc.  
425 Third Street, SW, Suite 800  
Washington, DC 20024

Re: FDA FOIA Request 2021-5762; *Judicial Watch, Inc. v. HHS*, 22-cv-00660-FYP

Dear Ms. Burke,

FDA has considered the withholdings identified in your November 7, 2022 email to U.S. Department of Justice attorney Jody Lowenstein regarding your Freedom of Information Act (FOIA) request number **2021-5762**. In that email, your client challenged two groups of withholdings: Group 1: redactions under Exemption (b)(5) to a May 14, 2021 email from Amanda Cohn; and Group 2: redactions under Exemptions (b)(3) and (b)(4) to a series of communications between HHS/FDA and the Medicines and Healthcare Products Regulatory Agency (MHRA).

Per the November 14, 2022 Joint Status Report filed in the above-referenced case, FDA has reviewed the challenged withholdings in good faith and, after consultation with outside agencies, is making a supplemental production with the hope of resolving plaintiff's objections without the need for judicial intervention or, at a minimum, narrowing the issues that would need to be resolved on summary judgment. Specifically, FDA has withdrawn all redactions under Exemption (b)(5) to the May 14, 2021 email from Amanda Cohn (Group 1). And with regard to the Group 2 records, FDA has withdrawn its assertion of Exemption (b)(4) and has significantly narrowed its assertion of Exemption (b)(3), as reflected in the attached supplemental production. Please note that we are reissuing pages with the same Bates numbers. They are intended to replace the previous versions of those documents. These records come from the FDA's Center for Biologics Evaluation and Research (CBER), and are Bates numbered FDA-CBER-2021-5762-00137, FDA-CBER-2021-5762-01064 to -01086 and FDA-CBER-2021-01095 to -01127. Accordingly, attached please find revised versions of the records identified in your November 7, 2022 email.

As explained in FDA's prior letters to you, FDA has withheld information under Exemption (b)(3), 5 U.S.C. § 552(b)(3). That exemption permits the withholding of information specifically exempted by statute. Here, we have applied Exemption (b)(3) to information specifically exempted under section 708 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 379(b)). Section 708 is applicable because the Group 2 records consist of communications with MHRA about drugs and contain information that (i) alerts the United States to the potential need for an investigation, (ii) was provided to FDA (and the United States Government) voluntarily under the condition that it not be released to the public, and (iii) is covered by, and subject to, a written agreement between FDA and MHRA. *See, e.g.,* The United Kingdom Medicines and Healthcare Products Regulatory Agency – FDA, Confidentiality Commitment, dated October 11, 2017 (available at [The United Kingdom Medicines and Healthcare Products Regulatory Agency – FDA, Confidentiality Commitment | FDA](#)).

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 552(b)(6), which your client has not challenged. That exemption protects information from disclosure when its release would cause




a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy. The (b)(6) withholdings in our original production have not been changed.

In determining to withhold such information, FDA considered 5 USC § 552(a)(8)(i), when applicable, and whether FDA reasonably foresees that disclosure of such information would harm an interest protected by the relevant exemption(s) and whether disclosure is prohibited by law. As you likely understand, FDA's ability to share confidential information pursuant to confidentiality commitments with foreign governments is vitally important to FDA. At a minimum, the harm that would be caused by releasing information provided to FDA under the condition that it not be released to the public is foreseeable and justifies FDA withholdings under Exemption (b)(3) in this production.

Please direct any questions regarding this response to Jody D. Lowenstein of the U.S. Department of Justice, at (202) 598-9280 or [jody.d.lowenstein@usdoj.gov](mailto:jody.d.lowenstein@usdoj.gov). FDA reserves its right to further explain and expand upon the legal bases summarized in this letter.

Sincerely,

Ricci J. Ward -  S

Digitally signed by Ricci J. Ward -  
Date: 2022.12.27 09:08:32 -05'00'

Ricci Ward for Beth Brockner Ryan  
Chief, Access Litigation and Freedom of Information Branch  
Division of Disclosure and Oversight Management  
Office of Communication Outreach and Development  
Center for Biologics Evaluation and Research

Attachments

cc:

Jody D. Lowenstein, Federal Programs Branch, USDOJ (By email)  
Seth I. Heller, Office of the Chief Counsel, FDA (By email)

**From:** Krause, Philip [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00C6330FEA0042FDB5571C3FDEF792ED-KRAUSE]  
**Sent:** 12/18/2020 2:57:10 PM  
**To:** Convisser, Jamie [Jamie.Convisser@mhra.gov.uk]  
**CC:** Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mogford, Jonathan [Jonathan.Mogford@mhra.gov.uk]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]  
**Subject:** RE: (b)(3)

Hi Jamie,

We agree as well. Thanks for the exchange!

Your summary is correct. I'm cc'ing Amanda Cohn at CDC who can provide the most up-to-date details about (b)(3) (b)(3). Obviously, (b)(3) not all of this is public so please hold these details confidential.

Warm regards,

Phil

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**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Friday, December 18, 2020 1:07 PM  
**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Hi Phil,

We all thought it was very useful to speak with you and colleagues earlier.

Could I please ask on behalf of the team, if you could confirm details of (b)(3) mentioned on the call? If I noted correctly, there was (b)(3) (b)(3)

Thanks very much

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

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**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 18 December 2020 12:10  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Hi Jamie, I confirm that we will participate. Thanks! Phil

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**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Friday, December 18, 2020 6:42 AM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Phil,

I've got the green light for a 1pm/8am meeting. I will set this up now. Please let me know asap if US colleague are unable to join.

Jamie

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**From:** Convisser, Jamie  
**Sent:** 18 December 2020 11:35  
**To:** 'Krause, Philip' <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Hi Phil,

I'm working on trying to set up a call for 1pm – I will confirm shortly (this would be 8am US time). We wouldn't be able to make tomorrow, but next week early we are looking to hold a small cluster meeting of key regulators to discuss key updates on (b)(3) too, so I'll keep you in the loop about this too.

All the best,

Jamie

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**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 17 December 2020 15:57  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Hi Jamie,

(b)(3)

Maybe it would be a good idea to set up a 30-minute call to further discuss (b)(3) so we each have as complete information as possible in deciding on next steps? We would also invite CDC, who may have additional updates. Our preference would be to talk on Saturday, because tomorrow is such a busy day for us working on the Moderna product. If Saturday isn't feasible, I'd like to suggest 7 a.m. or 8 a.m. US time, 1200 or 1300 UK time tomorrow, when we could also carve out some time. Though of course, if those possibilities wouldn't work for your team, we could look for another time.

Thanks!

Phil

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**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 1:55 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

Thanks for checking and sorry for not clarifying before - this information is not in the public domain so please could you not refer to (b)(3)

Many thanks

Jamie

**Jamie Convisser**

Head of International and Trade Policy

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b)(6)

Mobile: (b)(6)

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**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 18:28

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie,

Thank you very much. Would it be okay for us to mention this information about (b)(3) at our advisory committee meeting tomorrow?

Best wishes,  
Phil

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**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Wednesday, December 16, 2020 1:24 PM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Hi Phil,

I've received the following update from our experts:

(b)(3)

I hope this helps and should we have any further updates I will let you know.

All the best,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

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**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 16 December 2020 16:05  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Thanks!

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**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Wednesday, December 16, 2020 10:50 AM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Hi Phil,

We will definitely get a note over to you later today – our vigilance teams are caught up with meetings at the moment but have promised me some material later.

Thanks,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 15:31

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie,

Any updates? We appreciate whatever you or your team can tell us in advance of our public meeting tomorrow morning.

Thanks,

Phil

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**From:** Krause, Philip

**Sent:** Tuesday, December 15, 2020 2:44 PM

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Many thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Tuesday, December 15, 2020 1:12 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Dear Phil, Marion,

Thank you for your email – I have sent this on to relevant experts in our vigilance teams and will be in touch as soon as I hear back.

Kind regards,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

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**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 15 December 2020 15:18

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Jamie,

As you've probably heard, we're going back to our advisory committee on Thursday (b)(3)  
(b)(3) Do you have any  
update on what has happened (b)(3)  
(b)(3)

We'd be happy to discuss by teleconference tomorrow (Wednesday), or maybe it would be simpler, if possible, for you to just provide an email update.

Thanks!

Phil & Marion

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**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 12:04 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

Sorry I am unable to get the right experts on the line in time for this call – we will be in touch once I have a better idea on availability of our technical teams either for a quick call with FDA or for the wider global call.

Best regards,

Jamie

**Jamie Convisser**

Head of International and Trade Policy



Medicines and Healthcare products Regulatory Agency

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[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 09 December 2020 16:43

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie and June,

From our perspective, the more we can know about this before the advisory committee meeting that starts tomorrow morning US time, the better. If a more global ICMRA call isn't possible before then, we would still greatly appreciate the ability to talk with you about this. We have a lot of meetings today, but if it were possible to talk under our confidentiality agreement at least briefly at 1700 UK time, that would indeed be very helpful.

Here is a link that we can use, in the event that is deemed possible.

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

[Join meeting](#)

**Tap to join from a mobile device (attendees only)**

+1-210-795-0506 (b) (6) US Toll  
+1-877-465-7975 (b) (6) US Toll Free

**Join by phone**

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Thanks,

Phil

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**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 10:46 AM

**To:** Gruber, Marion <Marion.Grubert@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Cc:** Raine, Dr June <June.Raine@mhra.gov.uk>; Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>  
**Subject:** Re: (b)(3)

Thanks Marion

Jamie Convisser is liaising with the team - the idea is to offer a call to ICMRA main global regulators - but that may not be possible to set up today. Jamie will be in contact.

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Gruber, Marion <Marion.Grubert@fda.hhs.gov>  
**Sent:** Wednesday, December 9, 2020 3:35:47 PM  
**To:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Cc:** Raine, Dr June <June.Raine@mhra.gov.uk>; Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>  
**Subject:** RE: (b)(3)

Dear Jonathan,  
Thank you so much for this information. Our emails crossed. If possible, would you be available for a t-con today?  
Marion Gruber

---

**From:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Sent:** Wednesday, December 9, 2020 10:34 AM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>  
**Cc:** Raine, Dr June <June.Raine@mhra.gov.uk>; Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Gruber, Marion <Marion.Grubert@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>  
**Subject:** Re: (b)(3)

... attached are (b)(3) : hope that's helpful in the meantime.

If I can just remind - information shared under our confidentiality agreement.

Thanks

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Sent:** Wednesday, December 9, 2020 12:56 pm  
**To:** Marks, Peter; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** Re: (b)(3)

Thanks Peter - we'll liaise with our vaccines leads - I think the easiest thing will be for them to liaise directly, but we'll think about the best way to do this

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Sent:** Wednesday, December 9, 2020 10:03 am  
**To:** Mogford, Jonathan; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you very much for this information. It would be very helpful if our Office of Vaccines could receive additional details (b)(3) from MHRA under the terms of our mutual confidentiality agreement. I am copying the Director of our Office of Vaccines, Marion Gruber, so that she is aware.

Best Regards,  
Peter

---

Peter Marks, MD, PhD  
Director  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue

WO71-7232  
Silver Spring, MD 20993  
240-402-8116 voice  
301-595-1310 fax  
[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)



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---

**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 4:57 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>  
**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Subject:** (b)(3)

Dear Peter and Janet

(b)(3)

(b)(3)

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

Information sent out:

**Risk of allergic reactions**

## **Advice to Healthcare professionals**

This precautionary advice is being issued following two case reports of anaphylactoid reactions associated with administration of Pfizer BioNtech COVID-19 vaccine.

### **New advice:**

1. Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer BioNtech vaccine.
2. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.

-

### **Background**

There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

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For more information on the Department of Health's email policy, click

**DHTermsAndConditions**



**From:** Cohn, Amanda (CDC/DDID/NCIRD/OD) [anc0@cdc.gov]  
**Sent:** 12/21/2020 11:58:40 AM  
**To:** Convisser, Jamie [Jamie.Convisser@mhra.gov.uk]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]  
**CC:** Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mogford, Jonathan [Jonathan.Mogford@mhra.gov.uk]; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Martin, Stacey (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=75d5b37f96474b98892a56a967a0f55b-HHS-zmt0-cd]  
**Subject:** RE: (b)(3)  
**Attachments:** Anaphylaxis CLARK Dec 19 2020 Final.pptx

Hi Jamie,

I am adding my colleagues Tom Clark and Stacey Martin, we are happy to share more information with you. Attached are slides that were presented at a public meeting on Saturday. (b)(3)

(b)(3)

Thanks!  
Amanda

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Monday, December 21, 2020 10:24 AM  
**To:** Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran (FDA/CBER) <Doran.Fink@fda.hhs.gov>; Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>  
**Subject:** RE: (b)(3)

Hi Phil,

If Amanda wouldn't mind sharing (b)(3) that would be appreciated. We will ensure the details are treated confidentially.

Many thanks,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Sent:** 18 December 2020 19:57  
**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Cohn, Amanda C (CDC) <anc0@cdc.gov>  
**Subject:** RE: (b)(3)

Hi Jamie,

We agree as well. Thanks for the exchange!

Your summary is correct. I'm cc:ing Amanda Cohn at CDC who can provide the most up-to-date details about (b)(3). Obviously, (b)(3), not all of this is public so please hold these details confidential.

Warm regards,

Phil

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Friday, December 18, 2020 1:07 PM  
**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Hi Phil,

We all thought it was very useful to speak with you and colleagues earlier.

Could I please ask on behalf of the team, if you could confirm details of (b)(3) mentioned on the call? If I noted correctly, there was (b)(3).  
(b)(3).

Thanks very much

Jamie

**Jamie Convisser**  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)  
Direct line: (b)(6)  
Mobile: (b)(6)

---

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Sent:** 18 December 2020 12:10  
**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Hi Jamie, I confirm that we will participate. Thanks! Phil

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Friday, December 18, 2020 6:42 AM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Phil,

I've got the green light for a 1pm/8am meeting. I will set this up now. Please let me know asap if US colleague are unable to join.

Jamie

---

**From:** Convisser, Jamie

**Sent:** 18 December 2020 11:35

**To:** 'Krause, Philip' <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

I'm working on trying to set up a call for 1pm – I will confirm shortly (this would be 8am US time). We wouldn't be able to make tomorrow, but next week early we are looking to hold a small cluster meeting of key regulators to discuss key updates on (b)(3) too, so I'll keep you in the loop about this too.

All the best,

Jamie

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 17 December 2020 15:57

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Jamie,

(b)(3)

Maybe it would be a good idea to set up a 30-minute call to further discuss (b)(3) so we each have as complete information as possible in deciding on next steps? We would also invite CDC, who may have additional

updates. Our preference would be to talk on Saturday, because tomorrow is such a busy day for us working on the Moderna product. If Saturday isn't feasible, I'd like to suggest 7 a.m. or 8 a.m. US time, 1200 or 1300 UK time tomorrow, when we could also carve out some time. Though of course, if those possibilities wouldn't work for your team, we could look for another time.

Thanks!

Phil

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 1:55 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

Thanks for checking and sorry for not clarifying before - this information is not in the public domain so please could you not refer to (b)(3)

Many thanks

Jamie

**Jamie Convisser**

Head of International and Trade Policy

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b)(6)

Mobile: (b)(6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 18:28

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie,

Thank you very much. Would it be okay for us to mention this information about (b)(3) at our advisory committee meeting tomorrow?

Best wishes,  
Phil

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 1:24 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Phil,

I've received the following update from our experts:

(b)(3)

I hope this helps and should we have any further updates I will let you know.

All the best,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b)(6)

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---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 16:05

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 10:50 AM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Phil,

We will definitely get a note over to you later today – our vigilance teams are caught up with meetings at the moment but have promised me some material later.

Thanks,



Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 15:31

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie,

Any updates? We appreciate whatever you or your team can tell us in advance of our public meeting tomorrow morning.

Thanks,  
Phil

---

**From:** Krause, Philip

**Sent:** Tuesday, December 15, 2020 2:44 PM

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Many thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Tuesday, December 15, 2020 1:12 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Dear Phil, Marion,

Thank you for your email – I have sent this on to relevant experts in our vigilance teams and will be in touch as soon as I hear back.

Kind regards,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)  
Direct line: (b) (6)  
Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 15 December 2020 15:18  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Hi Jamie,

As you've probably heard, we're going back to our advisory committee on Thursday (b)(3)  
(b)(3) Do you have any  
update on what has happened (b)(3)  
(b)(3)

We'd be happy to discuss by teleconference tomorrow (Wednesday), or maybe it would be simpler, if possible, for you to just provide an email update.

Thanks!  
Phil & Marion

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 12:04 PM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Hi Phil,

Sorry I am unable to get the right experts on the line in time for this call – we will be in touch once I have a better idea on availability of our technical teams either for a quick call with FDA or for the wider global call.

Best regards,

Jamie

**Jamie Convisser**  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)  
Direct line: (b) (6)  
Mobile: (b) (6)

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 09 December 2020 16:43

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie and June,

From our perspective, the more we can know about this before the advisory committee meeting that starts tomorrow morning US time, the better. If a more global ICMRA call isn't possible before then, we would still greatly appreciate the ability to talk with you about this. We have a lot of meetings today, but if it were possible to talk under our confidentiality agreement at least briefly at 1700 UK time, that would indeed be very helpful.

Here is a link that we can use, in the event that is deemed possible.

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

[Join meeting](#)

**Tap to join from a mobile device (attendees only)**

+1-210-795-0506, (b) (6) US Toll  
+1-877-465-7975, (b) (6) US Toll Free

**Join by phone**

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Thanks,  
Phil

---

**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 10:46 AM

**To:** Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>; Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>

**Subject:** Re: (b)(3)

Thanks Marion

Jamie Convisser is liaising with the team - the idea is to offer a call to ICMRA main global regulators - but that may not be possible to set up today. Jamie will be in contact.

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: [REDACTED] (b) (6) (w)

---

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

**Sent:** Wednesday, December 9, 2020 3:35:47 PM

**To:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Marks, Peter <Peter.Marks@fda.hhs.gov>

**Cc:** Raine, Dr June <June.Raine@mhra.gov.uk>; Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>

**Subject:** RE: [REDACTED] (b)(3)

Dear Jonathan,

Thank you so much for this information. Our emails crossed. If possible, would you be available for a t-con today?

Marion Gruber

---

**From:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>

**Sent:** Wednesday, December 9, 2020 10:34 AM

**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

**Cc:** Raine, Dr June <June.Raine@mhra.gov.uk>; Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>

**Subject:** Re: [REDACTED] (b)(3)

... attached are [REDACTED] (b)(3) hope that's helpful in the meantime.

If I can just remind - information shared under our confidentiality agreement.

Thanks

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Sent:** Wednesday, December 9, 2020 12:56 pm  
**To:** Marks, Peter; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** Re: (b)(3)

Thanks Peter - we'll liaise with our vaccines leads - I think the easiest thing will be for them to liaise directly, but we'll think about the best way to do this

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Sent:** Wednesday, December 9, 2020 10:03 am  
**To:** Mogford, Jonathan; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you very much for this information. It would be very helpful if our Office of Vaccines could receive additional details (b)(3) from MHRA under the terms of our mutual confidentiality agreement. I am copying the Director of our Office of Vaccines, Marion Gruber, so that she is aware.

Best Regards,  
Peter

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Peter Marks, MD, PhD  
Director  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
WO71-7232  
Silver Spring, MD 20993  
240-402-8116 voice  
301-595-1310 fax  
[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)





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---

**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 4:57 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>  
**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Subject:** (b)(3)

Dear Peter and Janet

(b)(3)

(b)(3)

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

Information sent out:

### **Risk of allergic reactions**

### **Advice to Healthcare professionals**

This precautionary advice is being issued following two case reports of anaphylactoid reactions associated with administration of Pfizer BioNtech COVID-19 vaccine.

### **New advice:**

1. Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer BioNtech vaccine.
2. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.

-

### **Background**

There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

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**DHTermsAndConditions**

**From:** Convisser, Jamie [Jamie.Convisser@mhra.gov.uk]  
**Sent:** 12/21/2020 10:24:14 AM  
**To:** Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]  
**CC:** Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mogford, Jonathan [Jonathan.Mogford@mhra.gov.uk]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]  
**Subject:** RE: (b)(3)

Hi Phil,

If Amanda wouldn't mind sharing (b)(3) that would be appreciated. We will ensure the details are treated confidentially.

Many thanks,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Sent:** 18 December 2020 19:57  
**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Cohn, Amanda C (CDC) <anc0@cdc.gov>  
**Subject:** RE: (b)(3)

Hi Jamie,

We agree as well. Thanks for the exchange!

Your summary is correct. I'm cc:ing Amanda Cohn at CDC who can provide the most up-to-date details about (b)(3). Obviously, (b)(3) not all of this is public so please hold these details confidential.

Warm regards,

Phil

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Friday, December 18, 2020 1:07 PM  
**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

We all thought it was very useful to speak with you and colleagues earlier.

Could I please ask on behalf of the team, if you could confirm details of (b)(3) mentioned on the call? If I noted correctly, there was (b)(3)  
(b)(3)

Thanks very much

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b)(6)

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---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 18 December 2020 12:10

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Jamie, I confirm that we will participate. Thanks! Phil

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Friday, December 18, 2020 6:42 AM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Phil,

I've got the green light for a 1pm/8am meeting. I will set this up now. Please let me know asap if US colleague are unable to join.

Jamie

---

**From:** Convisser, Jamie

**Sent:** 18 December 2020 11:35

**To:** 'Krause, Philip' <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

I'm working on trying to set up a call for 1pm – I will confirm shortly (this would be 8am US time). We wouldn't be able to make tomorrow, but next week early we are looking to hold a small cluster meeting of key regulators to discuss key updates on (b)(3) too, so I'll keep you in the loop about this too.

All the best,

Jamie

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 17 December 2020 15:57

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Jamie,

(b)(3)

Maybe it would be a good idea to set up a 30-minute call to further discuss (b)(3) so we each have as complete information as possible in deciding on next steps? We would also invite CDC, who may have additional updates. Our preference would be to talk on Saturday, because tomorrow is such a busy day for us working on the Moderna product. If Saturday isn't feasible, I'd like to suggest 7 a.m. or 8 a.m. US time, 1200 or 1300 UK time tomorrow, when we could also carve out some time. Though of course, if those possibilities wouldn't work for your team, we could look for another time.

Thanks!

Phil

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 1:55 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

Thanks for checking and sorry for not clarifying before - this information is not in the public domain so please could you not refer to (b)(3)



Many thanks

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 18:28

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie,

Thank you very much. Would it be okay for us to mention this information about (b)(3) at our advisory committee meeting tomorrow?

Best wishes,  
Phil

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 1:24 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Phil,

I've received the following update from our experts:

(b)(3)

I hope this helps and should we have any further updates I will let you know.

All the best,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 16:05

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 10:50 AM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Phil,

We will definitely get a note over to you later today – our vigilance teams are caught up with meetings at the moment but have promised me some material later.

Thanks,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 15:31

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie,

Any updates? We appreciate whatever you or your team can tell us in advance of our public meeting tomorrow morning.

Thanks,  
Phil

---

**From:** Krause, Philip  
**Sent:** Tuesday, December 15, 2020 2:44 PM  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Many thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Tuesday, December 15, 2020 1:12 PM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Dear Phil, Marion,

Thank you for your email – I have sent this on to relevant experts in our vigilance teams and will be in touch as soon as I hear back.

Kind regards,

Jamie

**Jamie Convisser**  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)  
Direct line: (b) (6)  
Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 15 December 2020 15:18  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Hi Jamie,

As you've probably heard, we're going back to our advisory committee on Thursday (b)(3)  
(b)(3) Do you have any  
update on what has happened (b)(3)  
(b)(3)

We'd be happy to discuss by teleconference tomorrow (Wednesday), or maybe it would be simpler, if possible, for you to just provide an email update.

Thanks!  
Phil & Marion

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 12:04 PM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Hi Phil,

Sorry I am unable to get the right experts on the line in time for this call – we will be in touch once I have a better idea on availability of our technical teams either for a quick call with FDA or for the wider global call.

Best regards,

Jamie

**Jamie Convisser**  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)  
Direct line: (b) (6)  
Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 09 December 2020 16:43  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Hi Jamie and June,

From our perspective, the more we can know about this before the advisory committee meeting that starts tomorrow morning US time, the better. If a more global ICMRA call isn't possible before then, we would still greatly appreciate the ability to talk with you about this. We have a lot of meetings today, but if it were possible to talk under our confidentiality agreement at least briefly at 1700 UK time, that would indeed be very helpful.

Here is a link that we can use, in the event that is deemed possible.

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)  
Meeting password: (b) (6)

[Join meeting](#)

Tap to join from a mobile device (attendees only)

+1-210-795-0506, (b) (6) US Toll  
+1-877-465-7975, (b) (6) US Toll Free

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Thanks,  
Phil

---

**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 10:46 AM

**To:** Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>; Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>

**Subject:** Re: (b)(3)

Thanks Marion

Jamie Convisser is liaising with the team - the idea is to offer a call to ICMRA main global regulators - but that may not be possible to set up today. Jamie will be in contact.

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>

**Sent:** Wednesday, December 9, 2020 3:35:47 PM

**To:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Blair, Joan W. (CBER)

<Joan.Blair@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>

**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you so much for this information. Our emails crossed. If possible, would you be available for a t-con today?

Marion Gruber

---

**From:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>

**Sent:** Wednesday, December 9, 2020 10:34 AM

**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

**Cc:** Raine, Dr June <June.Raine@mhra.gov.uk>; Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>

**Subject:** Re: (b)(3)

... attached are (b)(3) hope that's helpful in the meantime.

If I can just remind - information shared under our confidentiality agreement.

Thanks

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>

**Sent:** Wednesday, December 9, 2020 12:56 pm

**To:** Marks, Peter; Woodcock, Janet

**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)

**Subject:** Re: (b)(3)

Thanks Peter - we'll liaise with our vaccines leads - I think the easiest thing will be for them to liaise directly, but we'll think about the best way to do this

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products

Regulatory Agency

T: (b) (6) (w)

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Sent:** Wednesday, December 9, 2020 10:03 am  
**To:** Mogford, Jonathan; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you very much for this information. It would be very helpful if our Office of Vaccines could receive additional details on (b)(3) from MHRA under the terms of our mutual confidentiality agreement. I am copying the Director of our Office of Vaccines, Marion Gruber, so that she is aware.

Best Regards,  
Peter

---

Peter Marks, MD, PhD  
Director  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
WO71-7232  
Silver Spring, MD 20993  
240-402-8116 voice  
301-595-1310 fax  
[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)



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---

**From:** Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Sent:** Wednesday, December 9, 2020 4:57 AM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>  
**Cc:** Raine, Dr June <June.Raine@mhra.gov.uk>; Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Subject:** (b)(3)

Dear Peter and Janet

(b)(3)

(b)(3)

(b)(3)

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

Information sent out:

### **Risk of allergic reactions**

#### **Advice to Healthcare professionals**

This precautionary advice is being issued following two case reports of anaphylactoid reactions associated with administration of Pfizer BioNtech COVID-19 vaccine.

#### **New advice:**

1. Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer BioNtech vaccine.
2. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.

-

#### **Background**

There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)



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For more information on the Department of Health's email policy, click

**DHTermsAndConditions**

**From:** Cohn, Amanda (CDC/DDID/NCIRD/OD) [anc0@cdc.gov]  
**Sent:** 12/18/2020 7:16:07 AM  
**To:** Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]  
**Subject:** Re: (b)(3)

Thanks so much Phil!

Get Outlook for iOS

---

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Sent:** Friday, December 18, 2020 7:12:19 AM  
**To:** Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>  
**Subject:** FW: (b)(3)

Hi Amanda and Nancy,

This is very short notice, but we'd like to invite you to join a short call at 8 am with MHRA (b)(3)  
(b)(3) I'll forward you the invitation separately—it should be fine to also invite others at CDC.

Thanks,  
Phil

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Friday, December 18, 2020 6:42 AM  
**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Phil,

I've got the green light for a 1pm/8am meeting. I will set this up now. Please let me know asap if US colleague are unable to join.

Jamie

---

**From:** Convisser, Jamie  
**Sent:** 18 December 2020 11:35  
**To:** 'Krause, Philip' <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Hi Phil,

I'm working on trying to set up a call for 1pm – I will confirm shortly (this would be 8am US time). We wouldn't be able to make tomorrow, but next week early we are looking to hold a small cluster meeting of key regulators to discuss key updates on (b)(3) too, so I'll keep you in the loop about this too.

All the best,

Jamie

---

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>

**Sent:** 17 December 2020 15:57

**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>

**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>

**Subject:** RE: (b)(3)

Hi Jamie,

(b)(3)

Maybe it would be a good idea to set up a 30-minute call to further discuss (b)(3) so we each have as complete information as possible in deciding on next steps? We would also invite CDC, who may have additional updates. Our preference would be to talk on Saturday, because tomorrow is such a busy day for us working on the Moderna product. If Saturday isn't feasible, I'd like to suggest 7 a.m. or 8 a.m. US time, 1200 or 1300 UK time tomorrow, when we could also carve out some time. Though of course, if those possibilities wouldn't work for your team, we could look for another time.

Thanks!

Phil

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>

**Sent:** Wednesday, December 16, 2020 1:55 PM

**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>

**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>

**Subject:** RE: (b)(3)

Hi Phil,

Thanks for checking and sorry for not clarifying before - this information is not in the public domain so please could you not refer to (b)(3)

Many thanks

Jamie

**Jamie Convisser**

Head of International and Trade Policy

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 16 December 2020 18:28

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie,

Thank you very much. Would it be okay for us to mention this information about (b)(3) at our advisory committee meeting tomorrow?

Best wishes,  
Phil

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 16, 2020 1:24 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Phil,

I've received the following update from our experts:

(b)(3)

I hope this helps and should we have any further updates I will let you know.

All the best,

Jamie

**Jamie Convisser**

Head of International and Trade Policy

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 16 December 2020 16:05  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Wednesday, December 16, 2020 10:50 AM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Hi Phil,

We will definitely get a note over to you later today – our vigilance teams are caught up with meetings at the moment but have promised me some material later.

Thanks,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 16 December 2020 15:31  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Hi Jamie,

Any updates? We appreciate whatever you or your team can tell us in advance of our public meeting tomorrow morning.

Thanks,  
Phil

---

**From:** Krause, Philip  
**Sent:** Tuesday, December 15, 2020 2:44 PM  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Many thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Tuesday, December 15, 2020 1:12 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Dear Phil, Marion,

Thank you for your email – I have sent this on to relevant experts in our vigilance teams and will be in touch as soon as I hear back.

Kind regards,

Jamie

**Jamie Convisser**

Head of International and Trade Policy

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 15 December 2020 15:18

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Jamie,

As you've probably heard, we're going back to our advisory committee on Thursday

(b)(3)

(b)(3)

update on what has happened

(b)(3)

Do you have any

(b)(3)

We'd be happy to discuss by teleconference tomorrow (Wednesday), or maybe it would be simpler, if possible, for you to just provide an email update.

Thanks!

Phil & Marion

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 12:04 PM

**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>

**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>

**Subject:** RE: (b)(3)

Hi Phil,

Sorry I am unable to get the right experts on the line in time for this call – we will be in touch once I have a better idea on availability of our technical teams either for a quick call with FDA or for the wider global call.

Best regards,

Jamie

**Jamie Convisser**

Head of International and Trade Policy

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>

**Sent:** 09 December 2020 16:43

**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Raine, Dr June <June.Raine@mhra.gov.uk>

**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>

**Subject:** RE: (b)(3)

Hi Jamie and June,

From our perspective, the more we can know about this before the advisory committee meeting that starts tomorrow morning US time, the better. If a more global ICMRA call isn't possible before then, we would still greatly appreciate the ability to talk with you about this. We have a lot of meetings today, but if it were possible to talk under our confidentiality agreement at least briefly at 1700 UK time, that would indeed be very helpful.

Here is a link that we can use, in the event that is deemed possible.

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

[Join meeting](#)

Tap to join from a mobile device (attendees only)

+1-210-795-0506, (b) (6) JS Toll

**Join by phone**

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Thanks,  
Phil

---

**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 10:46 AM

**To:** Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>; Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>

**Subject:** Re: (b)(3)

Thanks Marion

Jamie Convisser is liaising with the team - the idea is to offer a call to ICMRA main global regulators - but that may not be possible to set up today. Jamie will be in contact.

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>

**Sent:** Wednesday, December 9, 2020 3:35:47 PM

**To:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>; Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you so much for this information. Our emails crossed. If possible, would you be available for a t-con today?

Marion Gruber



**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 10:34 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>  
**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>  
**Subject:** Re: (b)(3)

... attached are (b)(3) hope that's helpful in the meantime.

If I can just remind - information shared under our confidentiality agreement.

Thanks

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 12:56 pm  
**To:** Marks, Peter; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** Re: (b)(3)

Thanks Peter - we'll liaise with our vaccines leads - I think the easiest thing will be for them to liaise directly, but we'll think about the best way to do this

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

---

**From:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Sent:** Wednesday, December 9, 2020 10:03 am

**To:** Mogford, Jonathan; Woodcock, Janet

**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)

**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you very much for this information. It would be very helpful if our Office of Vaccines could receive additional details (b)(3) from MHRA under the terms of our mutual confidentiality agreement. I am copying the Director of our Office of Vaccines, Marion Gruber, so that she is aware.

Best Regards,  
Peter

---

Peter Marks, MD, PhD  
Director  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
WO71-7232  
Silver Spring, MD 20993  
240-402-8116 voice  
301-595-1310 fax  
[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)



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---

**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 4:57 AM

**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Subject:** (b)(3)

Dear Peter and Janet

(b)(3)

(b)(3)

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

Information sent out:

### **Risk of allergic reactions**

#### **Advice to Healthcare professionals**

This precautionary advice is being issued following two case reports of anaphylactoid reactions associated with administration of Pfizer BioNtech COVID-19 vaccine.

#### **New advice:**

1. Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer BioNtech vaccine.
2. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.

-

### **Background**

There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

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For more information on the Department of Health's email policy, click

**DHTermsAndConditions**

**From:** Krause, Philip [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00C6330FEA0042FDB5571C3FDEF792ED-KRAUSE]  
**Sent:** 12/18/2020 7:12:19 AM  
**To:** Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]  
**Subject:** FW: (b)(3)

Hi Amanda and Nancy,

This is very short notice, but we'd like to invite you to join a short call at 8 am with MHRA (b)(3). I'll forward you the invitation separately—it should be fine to also invite others at CDC.

Thanks,  
Phil

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Friday, December 18, 2020 6:42 AM  
**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Phil,

I've got the green light for a 1pm/8am meeting. I will set this up now. Please let me know asap if US colleague are unable to join.

Jamie

---

**From:** Convisser, Jamie  
**Sent:** 18 December 2020 11:35  
**To:** 'Krause, Philip' <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Hi Phil,

I'm working on trying to set up a call for 1pm – I will confirm shortly (this would be 8am US time). We wouldn't be able to make tomorrow, but next week early we are looking to hold a small cluster meeting of key regulators to discuss key updates on (b)(3) too, so I'll keep you in the loop about this too.

All the best,

Jamie

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Sent:** 17 December 2020 15:57  
**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Hi Jamie,

(b)(3)

Maybe it would be a good idea to set up a 30-minute call to further discuss (b)(3) so we each have as complete information as possible in deciding on next steps? We would also invite CDC, who may have additional updates. Our preference would be to talk on Saturday, because tomorrow is such a busy day for us working on the Moderna product. If Saturday isn't feasible, I'd like to suggest 7 a.m. or 8 a.m. US time, 1200 or 1300 UK time tomorrow, when we could also carve out some time. Though of course, if those possibilities wouldn't work for your team, we could look for another time.

Thanks!

Phil

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Wednesday, December 16, 2020 1:55 PM  
**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>  
**Subject:** RE: (b)(3)

Hi Phil,

Thanks for checking and sorry for not clarifying before - this information is not in the public domain so please could you not refer to (b)(3)

Many thanks

Jamie

**Jamie Convisser**  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)  
Direct line: (b) (6)  
Mobile: (b) (6)

---

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Sent:** 16 December 2020 18:28

**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Raine, Dr June <June.Raine@mhra.gov.uk>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** RE: (b)(3)

Hi Jamie,

Thank you very much. Would it be okay for us to mention this information about (b)(3) at our advisory committee meeting tomorrow?

Best wishes,  
Phil

---

**From:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>  
**Sent:** Wednesday, December 16, 2020 1:24 PM  
**To:** Krause, Philip <Philip.Krause@fda.hhs.gov>; Raine, Dr June <June.Raine@mhra.gov.uk>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** RE: (b)(3)

Hi Phil,

I've received the following update from our experts:

(b)(3)

All the best,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b)(6)

Mobile: (b)(6)

---

**From:** Krause, Philip <Philip.Krause@fda.hhs.gov>  
**Sent:** 16 December 2020 16:05  
**To:** Convisser, Jamie <Jamie.Convisser@mhra.gov.uk>; Raine, Dr June <June.Raine@mhra.gov.uk>  
**Cc:** Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** RE: (b)(3)

Thanks!

---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Sent:** Wednesday, December 16, 2020 10:50 AM  
**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Hi Phil,

We will definitely get a note over to you later today – our vigilance teams are caught up with meetings at the moment but have promised me some material later.

Thanks,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU  
[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>  
**Sent:** 16 December 2020 15:31  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Hi Jamie,

Any updates? We appreciate whatever you or your team can tell us in advance of our public meeting tomorrow morning.

Thanks,  
Phil

---

**From:** Krause, Philip  
**Sent:** Tuesday, December 15, 2020 2:44 PM  
**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>  
**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Subject:** RE: (b)(3)

Many thanks!



---

**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Tuesday, December 15, 2020 1:12 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Dear Phil, Marion,

Thank you for your email – I have sent this on to relevant experts in our vigilance teams and will be in touch as soon as I hear back.

Kind regards,

Jamie

**Jamie Convisser**

Head of International and Trade Policy

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 15 December 2020 15:18

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Jamie,

As you've probably heard, we're going back to our advisory committee on Thursday (b)(3)  
(b)(3) Do you have any  
update on what has happened (b)(3)  
(b)(3)

We'd be happy to discuss by teleconference tomorrow (Wednesday), or maybe it would be simpler, if possible, for you to just provide an email update.

Thanks!

Phil & Marion

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**From:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>

**Sent:** Wednesday, December 9, 2020 12:04 PM

**To:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>

**Subject:** RE: (b)(3)

Hi Phil,

Sorry I am unable to get the right experts on the line in time for this call – we will be in touch once I have a better idea on availability of our technical teams either for a quick call with FDA or for the wider global call.

Best regards,

Jamie

**Jamie Convisser**

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[Jamie.convisser@mhra.gov.uk](mailto:Jamie.convisser@mhra.gov.uk)

Direct line: (b) (6)

Mobile: (b) (6)

---

**From:** Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>

**Sent:** 09 December 2020 16:43

**To:** Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Cc:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>

**Subject:** RE: (b)(3)

Hi Jamie and June,

From our perspective, the more we can know about this before the advisory committee meeting that starts tomorrow morning US time, the better. If a more global ICMRA call isn't possible before then, we would still greatly appreciate the ability to talk with you about this. We have a lot of meetings today, but if it were possible to talk under our confidentiality agreement at least briefly at 1700 UK time, that would indeed be very helpful.

Here is a link that we can use, in the event that is deemed possible.

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

[Join meeting](#)

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+1-877-465-7975, (b) (6) US Toll Free

**Join by phone**

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

Thanks,  
Phil

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**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 10:46 AM  
**To:** Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>; Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>  
**Subject:** Re: (b)(3)

Thanks Marion

Jamie Convisser is liaising with the team - the idea is to offer a call to ICMRA main global regulators - but that may not be possible to set up today. Jamie will be in contact.

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

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**From:** Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>  
**Sent:** Wednesday, December 9, 2020 3:35:47 PM  
**To:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>; Krause, Philip <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>  
**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you so much for this information. Our emails crossed. If possible, would you be available for a t-con today?

Marion Gruber

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**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 10:34 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>  
**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>; Gruber, Marion <[Marion.Gruber@fda.hhs.gov](mailto:Marion.Gruber@fda.hhs.gov)>; Blair, Joan W. (CBER) <[Joan.Blair@fda.hhs.gov](mailto:Joan.Blair@fda.hhs.gov)>  
**Subject:** Re: (b)(3)

...attached are (b)(3) hope that's helpful in the meantime.

If I can just remind - information shared under our confidentiality agreement.

Thanks

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

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**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 12:56 pm  
**To:** Marks, Peter; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** Re: (b)(3)

Thanks Peter - we'll liaise with our vaccines leads - I think the easiest thing will be for them to liaise directly, but we'll think about the best way to do this

Best regards

Jonathan

Jonathan Mogford

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

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**From:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Sent:** Wednesday, December 9, 2020 10:03 am  
**To:** Mogford, Jonathan; Woodcock, Janet  
**Cc:** Raine, Dr June; Convisser, Jamie; Gruber, Marion; Blair, Joan W. (CBER)  
**Subject:** RE: (b)(3)

Dear Jonathan,

Thank you very much for this information. It would be very helpful if our Office of Vaccines could receive additional details (b)(3) from MHRA under the terms of our mutual confidentiality agreement. I am copying the Director of our Office of Vaccines, Marion Gruber, so that she is aware.

Best Regards,  
Peter

---

Peter Marks, MD, PhD  
Director  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
WO71-7232  
Silver Spring, MD 20993  
240-402-8116 voice  
301-595-1310 fax  
[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)



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**From:** Mogford, Jonathan <[Jonathan.Mogford@mhra.gov.uk](mailto:Jonathan.Mogford@mhra.gov.uk)>  
**Sent:** Wednesday, December 9, 2020 4:57 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>  
**Cc:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>; Convisser, Jamie <[Jamie.Convisser@mhra.gov.uk](mailto:Jamie.Convisser@mhra.gov.uk)>  
**Subject:** (b)(3)

Dear Peter and Janet

(b)(3)

(b)(3)

Best regards

Jonathan

Jonathan Mogford

Policy Director,

UK Medicines and Healthcare Products  
Regulatory Agency

T: (b) (6) (w)

Information sent out:

## **Risk of allergic reactions**

### **Advice to Healthcare professionals**

This precautionary advice is being issued following two case reports of anaphylactoid reactions associated with administration of Pfizer BioNtech COVID-19 vaccine.

#### **New advice:**

1. Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer BioNtech vaccine.
2. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.

-

### **Background**

There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

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**From:** Cohn, Amanda (CDC/DDID/NCIRD/OD) [anc0@cdc.gov]  
**Sent:** 5/14/2021 1:46:04 PM  
**To:** Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]  
**CC:** Mbaeyi, Sarah A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da4de16472154335afbbd91258c63d83-HHS-vif6-cd]  
**Subject:** RE: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

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We have a meeting with Rochelle at 3:30 about if we should say anything or wait until we have more definitive information...I will let you know where we land. I'm not sure there is a right answer.

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Sent:** Friday, May 14, 2021 1:29 PM  
**To:** Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>  
**Cc:** Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>  
**Subject:** RE: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

Dear Amanda and Sarah,

I can live with this as well.

Please let me know if you want to connect about the adverse event issue later today. Seems like work is still ongoing, but let me know. Thanks.

Best Regards,  
Peter

---

**From:** Gruber, Marion <Marion.Gruber@fda.hhs.gov>  
**Sent:** Friday, May 14, 2021 1:11 PM  
**To:** Cohn, Amanda C (CDC) <anc0@cdc.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Cc:** Mbaeyi, Sarah A (CDC) <vif6@cdc.gov>  
**Subject:** RE: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

I am fine with this language.  
Marion

---

**From:** Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>  
**Sent:** Friday, May 14, 2021 1:08 PM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>  
**Cc:** Mbaeyi, Sarah A (CDC) <vif6@cdc.gov>  
**Subject:** [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

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