

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

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) (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
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10 South Colonnade, Canary Wharf, London E14 4PU
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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>
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: [REDACTED] (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: [REDACTED] (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 [REDACTED] (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: [REDACTED] (b)(3)

Hi Jamie,

[REDACTED] (b)(3)

Maybe it would be a good idea to set up a 30-minute call to further discuss [REDACTED] (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: [REDACTED] (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 [REDACTED] (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

Direct line: [REDACTED] (b) (6)

Mobile: [REDACTED] (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: [REDACTED] (b)(3)

Hi Jamie,

Thank you very much. Would it be okay for us to mention this information about [REDACTED] (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)

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

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>

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

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,

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

Direct line: (b) (6)

Mobile: (b) (6)

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

Sent: 16 December 2020 15:31

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,

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>; 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)

Many thanks!

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

Sent: Tuesday, December 15, 2020 1:12 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)

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
Direct line: (b) (6)
Mobile: (b) (6)

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: 15 December 2020 15:18
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>
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>
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
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](tel:+1-210-795-0506), (b) (6) US Toll
[+1-877-465-7975](tel:+1-877-465-7975), (b) (6) US Toll Free

Join by phone

[+1-210-795-0506](tel:+1-210-795-0506) US Toll

[+1-877-465-7975](tel:+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>

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

To: Gruber, Marion <Marion.Gruber@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: [REDACTED] (b) (6) [REDACTED] (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

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



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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)

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: 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

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) (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>