
From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/2/2020 4:23:08 PM
To: Gregory W. Terman [gwt@uw.edu]
Subject: Re: Redesigning+opioids+may+not+prevent+their+fatal+side+effect

Will do. They are now part of our new neuroscience office. I will forward your email. Jw

From: Gregory W. Terman <gwt@uw.edu>
Date: March 2, 2020 at 2:20:37 PM MST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Fwd: Redesigning+opioids+may+not+prevent+their+fatal+side+effect

Hi Janet,

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Best Regards,
Greg Terman

<https://www.sciencemag.org/news/2020/02/redesigning-opioids-may-not-prevent-their-fatal-side-effect>

Gregory Terman MD PhD
Professor
Department of Anesthesiology and Pain Medicine
and the Graduate Program in Neuroscience
University of Washington
Seattle, Washington 98195
Office Phone: 206-616-2668
Office fax: 206-543-2958

From: Mark Eisner [eisner.mark@gene.com]
Sent: 3/28/2020 11:47:14 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Eric Olson [olson@gene.com]; Natasha Jarrett [natasha.jarrett@roche.com]
Subject: Re: Information request

Dear Dr. Woodcock,

We will provide you a written response today that addresses the anticipated Actemra supply in the US for the next six months. I am copying my colleagues Eric Olson, who heads US Regulatory Affairs at Genentech, and Natasha Jarrett, who is Global Head of Regulatory Affairs for Immunology, Infectious Disease, Ophthalmology, and Neuroscience Products.

Best regards,

Mark

Mark D. Eisner, MD, MPH
Senior Vice President, Product Development Immunology, Infectious Disease, and Ophthalmology
Genentech, Inc., a member of the Roche Group
Telephone: 650-467-5524 Mobile: 415-307-2042

For administrative assistance, please contact Mary Biggs at:
email: biggs.mary@gene.com telephone: 650-296-2867

On Sat, Mar 28, 2020 at 6:02 AM Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Could someone provide me or have a discussion with me about anticipated supplies of Actemra in the US over the next six months? Thanks very much. Janet Woodcock

From: Eric Olson [olson.eric@gene.com]
Sent: 3/28/2020 3:40:53 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Natasha Jarrett [natasha.jarrett@roche.com]; Mark Eisner [markde@gene.com]
Subject: Re: Information request

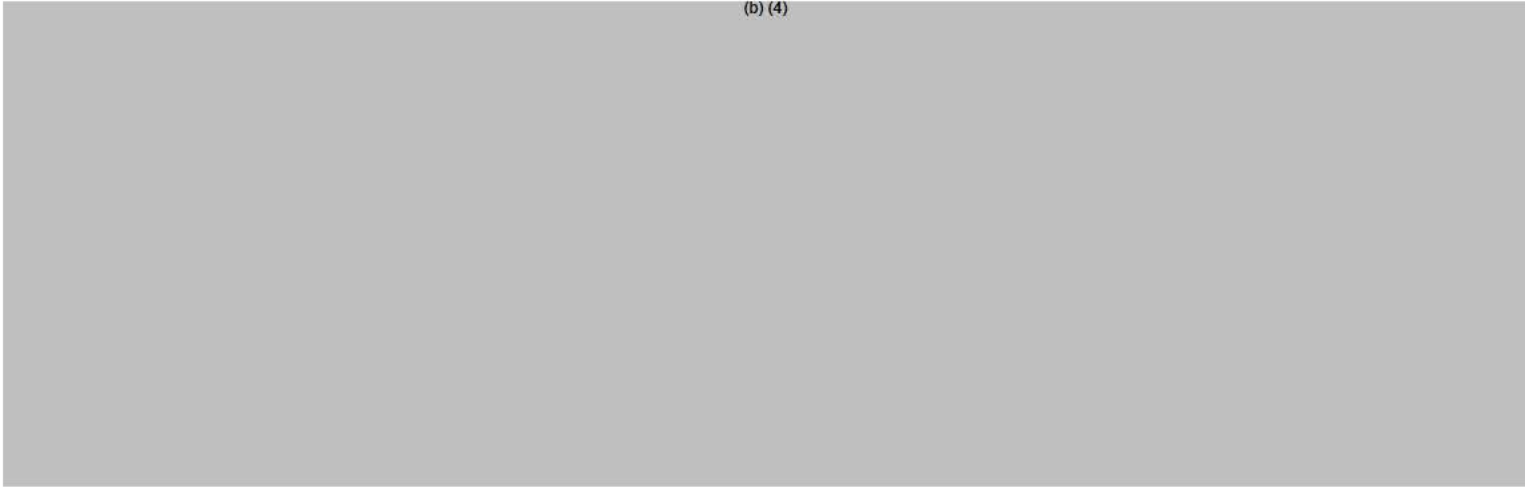
Hi Dr. Woodcock - enclosed below is information in response to your question on Actemra demand. As I'm sure you can imagine the situation remains fluid so these are our best current projections. We have tried to anticipate some additional questions you may have beyond your question on supply over the next 6 months.

My colleagues and I are on standby to answer any additional questions you may have about our supply / our recent experiences with Actemra use to treat C19. My mobile phone is below and we are all essentially on call 24/7 right now (as it seems you and your team are !!). Eric

ACTEMRA US SUPPLY SUMMARY - 6 MONTHS

KEY SUMMARY AND INSIGHTS:

(b) (4)



GLOBAL SUPPLY SUMMARY

(b) (4)

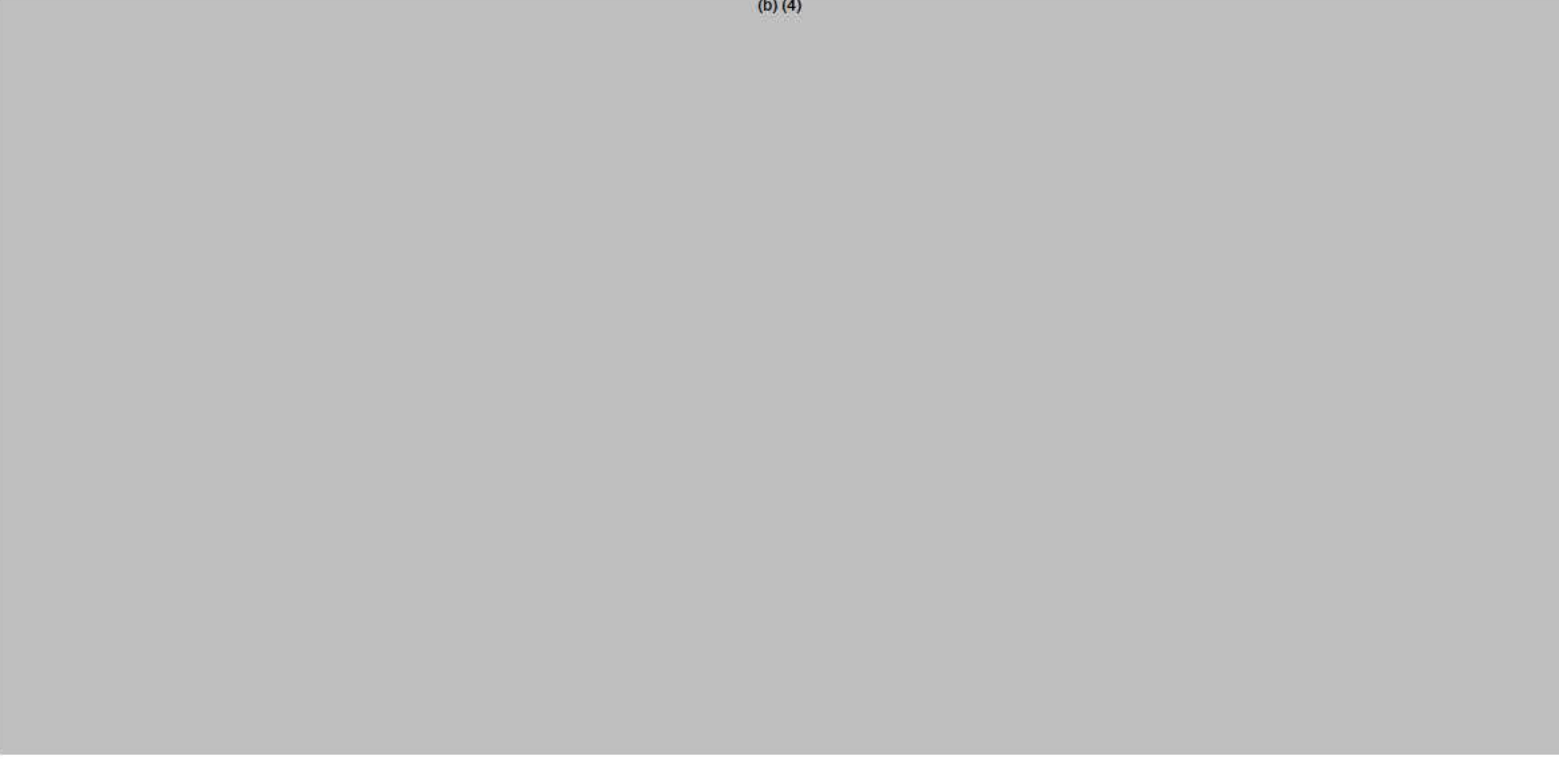


ACTEMRA DEMAND ESTIMATES

(b) (4)

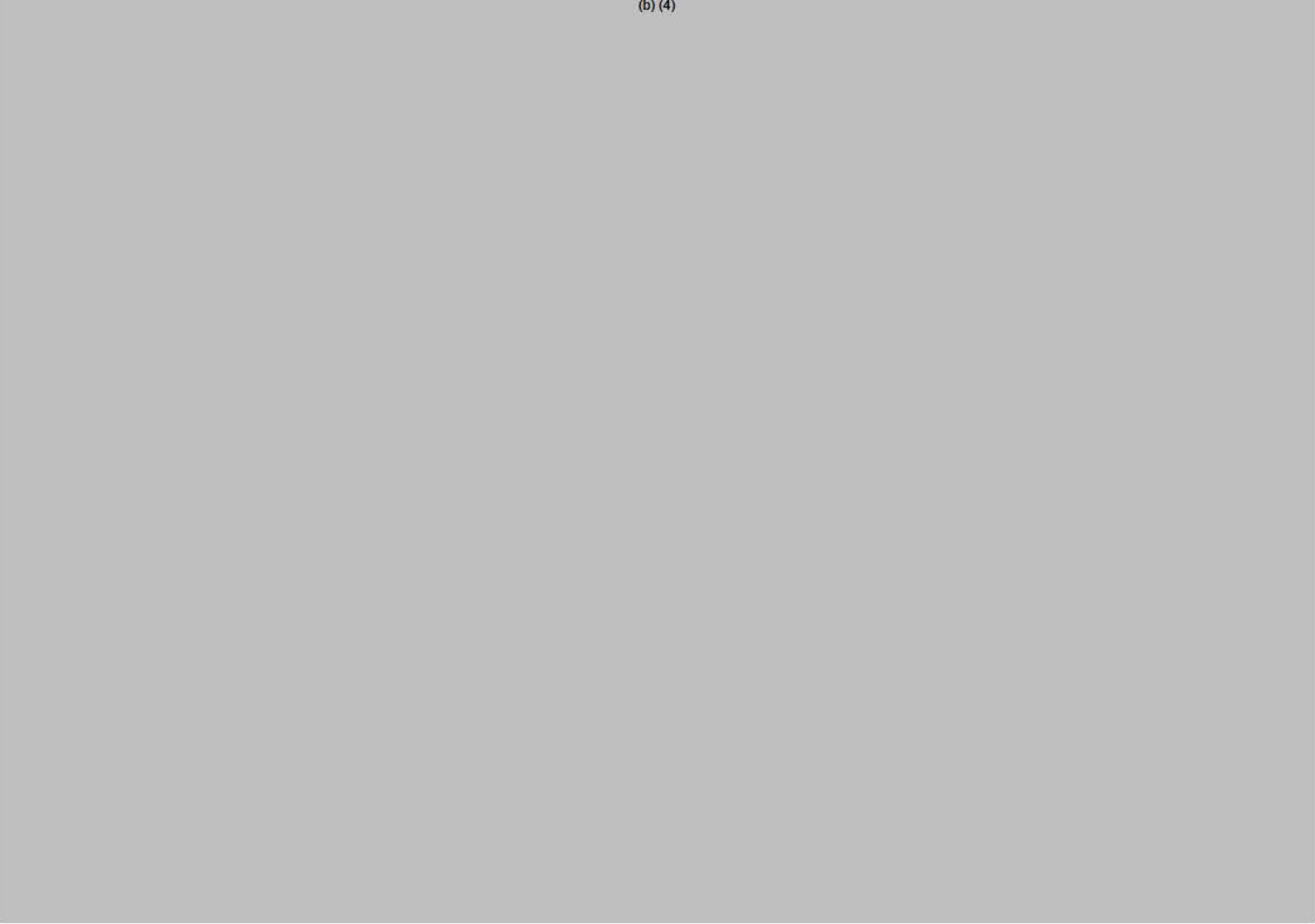


(b) (4)

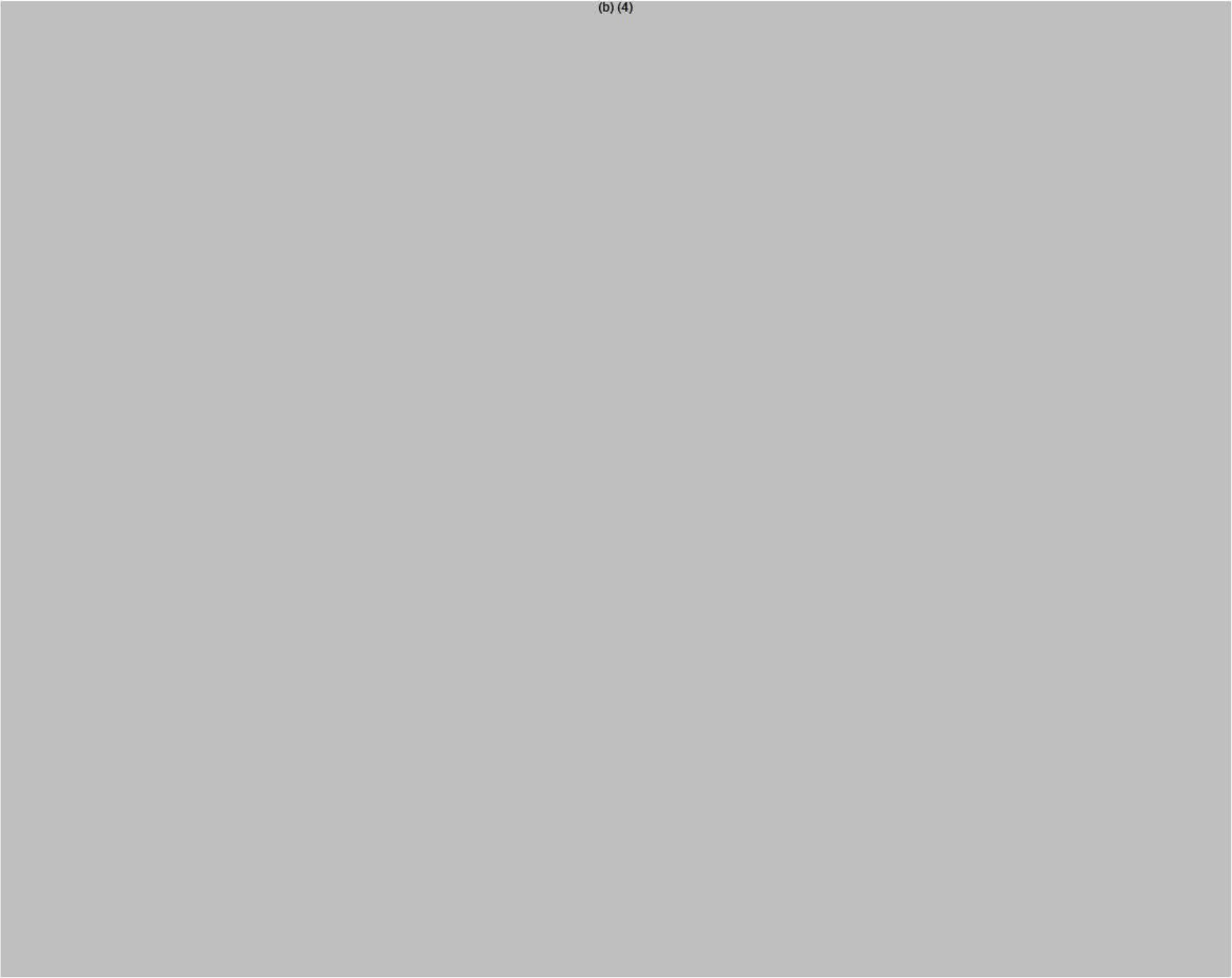
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SUPPLY MITIGATION SUMMARY

(b) (4)

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(b) (4)



DRUG SUBSTANCE MANUFACTURE

The approval of Actemra IV drug substance manufacturing at the Vacaville site was granted by FDA on 27th March, which was a crucial step to ensure a continued Actemra IV Drug Product supply. This allows:

(b) (4)



--

Eric Olson
Vice President, US Product Development Regulatory
Genentech, A Member of the Roche Group
+1 (650) 303-0978
olson@gene.com

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Sent: 3/2/2020 9:01:52 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: Redesigning+opioids+may+not+prevent+their+fatal+side+effect

Thanks Janet. I'm NOT really begging for more work but I would like to be helpful and turning down opportunities in order to avoid conflicts (when FDA no longer has interest in my help) might not be reasonable.

Best Regards,
Greg

On Mar 2, 2020, at 1:23 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

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From: Gregory W. Terman [gwt@uw.edu]
Sent: 3/2/2020 4:18:35 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group
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Office fax: 206-543-2958

From: Pao, William [william.pao@roche.com]
Sent: 5/19/2020 1:20:34 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Bugin, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]
Subject: RE: Neutralizing antibody in COVID19 meeting

Thank you, Janet.
Best,
William

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, May 19, 2020 2:41 AM
To: william.pao@roche.com; Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: Neutralizing antibody in COVID19 meeting

Dear Dr. Pao, we would be delighted if you would join this hour meeting, which will be held on this Wed. Kevin Bugin who is our program manager can provide the details. Thanks for your interest! Janet W

From: Bugin, Kevin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=735D396F29CE480A88DE9E6C2B0F424E-BUGINK]
Sent: 5/18/2020 8:54:43 PM
To: william.pao@roche.com
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Neutralizing antibody in COVID19 meeting

Hi Dr. Pao,

I will send you the invite for the meeting shortly. We'll be sending out some additional materials in advance of the meeting sometime tomorrow. Kind regards,

Kevin

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 18, 2020 8:41 PM
To: william.pao@roche.com; Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: Neutralizing antibody in COVID19 meeting

Dear Dr. Pao, we would be delighted if you would join this hour meeting, which will be held on this Wed. Kevin Bugin who is our program manager can provide the details. Thanks for your interest! Janet W

From: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Sent: 5/13/2020 12:06:37 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Holmes, Tina E. [Holmes.Tina@mayo.edu]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Thomas, Ashley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9909a538624847a09f76ec7c659ef59d-Ashley.Thom]
Subject: RE: Introduction

Thank you both

From: Marks, Peter [mailto:Peter.Marks@fda.hhs.gov]
Sent: Wednesday, May 13, 2020 11:04 AM
To: Woodcock, Janet; Farrugia, Gianrico, M.D.; Lenihan, Keagan; Holmes, Tina E.; Tierney, Julia
Cc: Thomas, Ashley
Subject: [EXTERNAL] RE: Introduction

Dear Dr. Farrugia,

My pleasure to have this conversation as well.

(Ashley – Julie Tierney can help find time on my calendar.)

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, May 13, 2020 12:01 PM
To: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Holmes, Tina E. <Holmes.Tina@mayo.edu>
Cc: Thomas, Ashley <Ashley.Thomas@fda.hhs.gov>
Subject: RE: Introduction

Sure. Ms Thomas, copied on this email, can set up a time for the three of us. Janet W

From: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>
Sent: Wednesday, May 13, 2020 11:38 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Holmes, Tina E. <Holmes.Tina@mayo.edu>
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From: Lenihan, Keagan [mailto:Keagan.Lenihan@fda.hhs.gov]
Sent: Wednesday, May 13, 2020 10:20 AM

To: Farrugia, Gianrico, M.D.; Woodcock, Janet; Marks, Peter

Subject: [EXTERNAL] Introduction

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Thank you Dr. Marks and Dr. Woodcock in advance for your help here.

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Happy to discuss, Dr. Farrugia. Janet W

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