FDA U.S. FOOD & DRUG ADMINISTRATION

August 19, 2020

In Response Refer to File: 2020-2623

Austin Evers
American Oversight
1030 15th Street NW, Suite B255
Washington, DC 20005

Dear Mr. Evers,

This is in response to your Freedom of Information Act (FOIA) letter dated March 17, 2020, in which you requested, for the date range of 1/10/2020 - 6/18/2020, Janet Woodcock emails with 24 listed external entities and individuals identified in column B of the letter. Your request was received in the Center for Drug Evaluation and Research on March 30, 2020.

The releasable documents are enclosed. After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under exemption (b)(4) of the FOIA, 5 U.S.C. § 552, as amended and delineated below:

> Exemption (b)(4) permits the withholding of "trade secrets" (TS) and /or commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

The following charges may be included in a monthly invoice:

Reproduction: $0.00 *Search: $0.00* *Review: $0.00* *Other: $1.00 (CD)* *TOTAL: $1.00*

The above total may not reflect final charges for this request.

PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.

This concludes the response for the Center for Drug Evaluation and Research. Please be advised that your request may have been submitted to one or more other component offices within FDA to conduct a search for records. These offices will reply to you directly. If we can be of further assistance to you, please do not hesitate to contact Gary Jackson at 240-402-6518.

Sincerely,

Eli Landy -S

Digitally signed by Eli Landy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Eli Landy -S, 0.9.2342.19200300.100.1.1=2000482461
Date: 2020.08.19 14:15:53 -04'00'

Eli Landy
Lead Regulatory Counsel
Division of Information Disclosure Policy
Office of Regulatory Policy
Center for Drug Evaluation and Research

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane
Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Please clearly mark both the envelope and your letter or email "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Katherine Uhl at 301-796-8975. You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Enclosure: Woodcock Records (1 CD)

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,
I wonder if I could get contact information for the person (or people) who took over at FDA in the analgesic and anesthetic division when Sharon retired. Thie attached news item in Science (essentially mimicking what I said on the advisory panel for oliceridine the first time around) reminded me of a long silence for me from FDA. For example, it dawns on me that I have not been asked to help on an advisory panel in the last year and I wonder whether I can do more good for the pain field by avoiding industry conflicts to help FDA (which has been my MO to this point in continuing my SGE status) or whether I should instead accept invitations from industry claiming to help them make analgesics safer. For the first time I am getting more requests for help from CDC than from FDA. I would appreciate the opportunity to reach out to Sharon's successor to offer my help personally but admit that I have kind of lost track of who that is. Thanks for your help in this regard.

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)

SUPPLY MITIGATION SUMMARY

(b) (4)

(b) (4)

[redacted]

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)

[redacted]

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

On Sat, Mar 28, 2020 at 8:47 AM Mark Eisner <markde@gene.com> wrote:

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Mark D. Eisner, MD, MPH
Senior Vice President, Product Development Immunology, Infectious Disease, and Ophthalmology
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email: biggs.mary@gene.com telephone: 650-296-2867

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

From: Gregory W. Terman [gwt@uw.edu]
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:

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

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Subject: Fwd: Redesigning+opioids+may+not+prevent+their+fatal+side+effect

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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: 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>
Subject: RE: Introduction

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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

Hello Dr. Farrugia,

To follow up on the conversation with the Commissioner yesterday, I wanted to introduce you to Dr. Woodcock, who is leading the response on therapeutics, and Dr. Marks, who is leading the vaccine response. Both of them would be happy to chat with you about the work going on at Mayo and their new roles in the COVID response. Please let me know if you need anything else.

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

Thanks,
Keagan

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Sent: 5/13/2020 12:04:13 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]; 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]
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Sent: Wednesday, May 13, 2020 10:20 AM
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Sent: 5/13/2020 11:38:09 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; farrugia.gianrico@mayo.edu; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
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Happy to discuss, Dr. Farrugia. Janet W

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Subject: Introduction

Hello Dr. Farrugia,

To follow up on the conversation with the Commissioner yesterday, I wanted to introduce you to Dr. Woodcock, who is leading the response on therapeutics, and Dr. Marks, who is leading the vaccine response. Both of them would be happy to chat with you about the work going on at Mayo and their new roles in the COVID response. Please let me know if you need anything else.

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

Thanks,
Keagan