



Bloomberg L.P.

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30 August 2021

Ms. Sarah B. Kotler, JD  
Director, Division of Freedom of Information  
Food & Drug Administration  
5630 Fishers Lane  
Room 1050  
Rockville, MD 20857

## **FREEDOM OF INFORMATION ACT REQUEST**

### **EXPEDITED PROCESSING REQUESTED**

Dear Ms. Kotler:

Pursuant to the Freedom of Information Act, 5 U.S.C. Section 552 et seq. ("FOIA"), I request a search. I am seeking information about any interactions between the Federal Drug Administration and Neuralink, a California-based company.

My request concerns Neuralink's work on brain-implant devices. I seek any calendar entries, phone logs, emails, letters, file documents, memorandums, and meeting notes generated or maintained by current and former FDA personnel around Neuralink's potential brain devices. The timeframe is Jan 1, 2019, through the present day. Herein after, these are known as "the Records."

This request is ongoing, seeking copies of (or access to) all Records as they are filed with the FDA. I am further requesting that the Records be provided to me on computer files or, if not maintained on computer files, in the same format as they are currently maintained at the FDA.

I am a reporter for Bloomberg News, an accredited and recognized news-gathering organization. I request the Records to inform the public about matters of public concern. As a representative of the news media, I am only required to pay for the direct cost of duplication after the first 100 pages. Please waive all applicable fees. In the event a fee waiver is not granted, I agree to pay reasonable fees for the Records, including actual costs up to \$250. If you estimate that actual costs will exceed this amount, please contact me so that I may make the appropriate arrangements for payment.



I accept clearly releasable information.

I request that these materials be subject to expedited processing on an ongoing basis: Bloomberg News is engaged in the dissemination of information to the public and the subject matter related to this request –how the government is maintaining oversight over critical devices that could affect patients’ brain and neurological health – is a matter of great public interest, debate, and urgency. I certify that my statements concerning the need for expedited processing are true and correct to the best of my knowledge and belief.

FOIA requires that your agency respond to my request for expedited treatment within 10 business days. In the event your agency denies my request for expedited treatment, whether through your agency’s affirmative denial of the request for expedited treatment or through your agency’s failure to respond to the request for expedited treatment, then FOIA requires that your agency nonetheless respond to the underlying request for information within 20 business days of receipt of this letter. This request is segregable, and your agency may not withhold entire records because of one section that you believe is exempt from disclosure. Under federal law, if you choose to withhold any such parts of the records from disclosure, you must specify in a written response the factual and legal basis for withholding any part of the Records.

Please contact me if I may assist in your office's response to this request. As I am making this request as a journalist and this information is of timely value, I would appreciate your communicating with me by telephone or email, rather than by mail, if you have questions regarding this request.

Thank you for your assistance.

Sincerely,

Sarah McBride, Reporter  
Bloomberg News  
Pier 3, Suite 191  
San Francisco, CA 94105  
[smcbride24@bloomberg.net](mailto:smcbride24@bloomberg.net)  
415-617-7336

CC: Katherine K. Graham, Newsroom Counsel

## Exhibit 2

From: [Candace.Boston@fda.hhs.gov](mailto:Candace.Boston@fda.hhs.gov) At: 02/03/22 14:22:29 UTC-8:00  
To: Sarah McBride (BLOOMBERG/ NEWSROOM: ), [FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov)  
Subject: RE: [EXTERNAL] Fwd:FDA Receipt of FOI Request Control # 2021-5750

Hi Sarah-

I hope you are well. CDRH currently has a backlog of FOIA requests. We currently have approximately 1,570 FOIA requests ahead of your request in our queue. We process requests in a first-in, first-out manner. Therefore, your request is not expected to come up in our queue for processing for at least 12 more months. We are working on adding additional personnel, therefore it is possible we will be able to get to your request sooner to get it closed out, but as of right now, that is the estimate. I hope this information is helpful. If I can be of any more assistance, please let me know. Thank you,

Candace

### **Candace Boston**

*Director, Division of Information Disclosure*

**Center for Devices and Radiological Health  
Office of Communication and Education  
U.S. Food and Drug Administration**

**Building 32, Rm 4212**

Tel: 240-402-3736

[candace.boston@fda.hhs.gov](mailto:candace.boston@fda.hhs.gov)



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: [CDRH Customer Service Survey](#)

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**From:** Sarah McBride (BLOOMBERG/ NEWSROOM:)  
<[smcbride24@bloomberg.net](mailto:smcbride24@bloomberg.net)>  
**Sent:** Thursday, February 03, 2022 11:50 AM  
**To:** Boston, Candace <[Candace.Boston@fda.hhs.gov](mailto:Candace.Boston@fda.hhs.gov)>; FDA FOIA  
<[FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Fwd:FDA Receipt of FOI Request Control #  
2021-5750

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

Hey Candace, how's it going?

I'd love a sense of the time frame on this request. Could you please let me know?

A big thank you

Sarah

From: Sarah McBride (BLOOMBERG/ NEWSROOM:)  
At: 01/25/22 12:14:39 UTC-8:00  
  
To: [Candace.Boston@fda.hhs.gov](mailto:Candace.Boston@fda.hhs.gov),  
[FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov)  
Subject: RE: [EXTERNAL] Fwd:FDA Receipt of  
FOI Request Control # 2021-5750

Thank you!

.....

Sarah McBride, Reporter, Bloomberg News  
+1 415 617 7336  
[@mcbridesg](https://www.linkedin.com/in/mcbridesg) <https://www.linkedin.com/in/mcbridesarah/>

From: [FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov) At: 01/25/22  
12:13:24 UTC-8:00

To: [Sarah McBride \(BLOOMBERG/](mailto:Sarah%20McBride%20(BLOOMBERG%20NEWSROOM%20%26%20FOIA%20@%20fda.hhs.gov))

NEWSROOM: ) , [Candace.Boston@fda.hhs.gov](mailto:Candace.Boston@fda.hhs.gov)

Subject: RE: [EXTERNAL] Fwd:FDA  
Receipt of FOI Request Control #  
2021-5750

Sarah,

Your request is open to CDRH, I have copied Candace so that she can provide an estimate of response.

Regards,

Katherine

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**From:** Sarah McBride (BLOOMBERG/NEWSROOM:)

[<smcbride24@bloomberg.net>](mailto:smcbride24@bloomberg.net)

**Sent:** Tuesday, January 25, 2022 3:09 PM

**To:** FDA FOIA

[<FDAFOIA@fda.hhs.gov>](mailto:FDAFOIA@fda.hhs.gov)

**Subject:** [EXTERNAL] Fwd:FDA  
Receipt of FOI Request Control #  
2021-5750

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Hi there

How are you? I wanted to check in on the status of this FOIA request. Any sense of where it is in line and how long it might take to fulfill?

Thank you so much!

Sarah

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Sarah McBride

Reporter

Bloomberg News

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Sarah McBride, Reporter, Bloomberg  
News  
+1 415 617 7336  
[@mcbridesg](mailto:mcbridesg)  
[https://www.linkedin.com/in/  
mcbridesarah/](https://www.linkedin.com/in/mcbridesarah/)

From: [FDA\\_FOI@fda.gov](mailto:FDA_FOI@fda.gov) At:  
09/02/21 04:42:50 UTC-7:00

To: [Sarah McBride \(BLOOMBERG/  
NEWSROOM: \)](#)

Cc: [FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov)

Subject: FDA Receipt of FOI  
Request Control # 2021-5750

Control number: 2021-5750

Please find the attached  
acknowledgement  
regarding your FOIA  
request.

Note: Do NOT reply directly  
to this E-mail



Bloomberg L.P.

731 Lexington Ave  
New York, NY 10022

Tel +1 212 318 2000  
bloomberg.com

23 January 2023

Ms. Sarah B. Kotler, JD  
Director, Division of Freedom of Information  
Food & Drug Administration  
5630 Fishers Lane  
Room 1050  
Rockville, MD 20857

**FREEDOM OF INFORMATION ACT REQUEST/FOLLOW-ON REQUEST  
EXPEDITED PROCESSING REQUESTED**

Dear Ms. Kotler:

Pursuant to the Freedom of Information Act, 5 U.S.C. Section 552 et seq. ("FOIA"), I request a narrowing of my original search request, filed on Aug. 30, 2021. My original request is 2021-5750, and by narrowing it, I am hoping to speed up the response time. My understanding is I will not lose my place in the line of requests. This is a follow-on to that original request.

Original request:

I am seeking information about any interactions between the Federal Drug Administration and Neuralink, a California-based company.

My request concerns Neuralink's work on brain-implant devices. I seek any calendar entries, phone logs, emails, letters, file documents, memorandums, and meeting notes generated or maintained by current and former FDA personnel around Neuralink's potential brain devices. The timeframe is Jan 1, 2019, through the present day. Herein after, these are known as "the Records."

**Narrowed follow-on request:**

**I am seeking information about any interactions between the Federal Drug Administration and Neuralink, a California-based company founded by entrepreneur Elon Musk. Other key personnel include Shivon Zilis and Max Hodak. I believe there is also communication outside of device approval that occurred with FDA leaders. Specifically, I am seeking communications between Neuralink and the following FDA officials:**



**CDRH Center Director Jeff Shuren  
Office of Policy Director and Deputy Center Director Ellen Flannery  
Office of Strategic Partnerships/Technology Innovation Director Suzanne Schwartz**

**I am also seeking emails, notes, word documents, phone logs, meeting notes, and calendar entries generated by or cc'ing any of those FDA officials that reference Neuralink or its executives. The timeframe is Jan 1, 2019, through the day the FDA conducts the searches. Herein after, these are known as "the Records."**

This request is ongoing, seeking copies of (or access to) all Records as they are filed with the FDA. I am further requesting that the Records be provided to me on computer files or, if not maintained on computer files, in the same format as they are currently maintained at the FDA.

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Thank you for your assistance.

Sincerely,

Sarah McBride, Reporter  
Bloomberg News  
Pier 3, Suite 191  
San Francisco, CA 94105  
[smcbride24@bloomberg.net](mailto:smcbride24@bloomberg.net)  
415-617-7336

CC: Katherine K. Graham, Newsroom Counsel