

Exhibit 3

Britney Long

From: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
Sent: Tuesday, November 7, 2023 12:02 PM
To: Marc Dudley
Subject: RE: [EXTERNAL] FOIA Control #2023-7590 [IR#1090]

Hi, Marc. Please see this additional information from CBER:

CBER's FOIA resources are currently stretched to capacity due to CBER marshaling its resources to comply with court-ordered record productions that are without precedent in volume and time to produce. Recently, CBER has been ordered to collectively produce 90,000 to 180,000 pages per month (from July 2023 to June 2025) in *Pub. Health & Med. Pros. for Transparency ("PHMPT") v. FDA*, Case No. 4:21-cv-1058 (N.D. Tex.) and *PHMPT & Stephanie and Patrick de Garay v. FDA*, Case No. 4:22-cv-915 (N.D. Tex.). Further, beginning in fiscal year 2019, the number and complexity of overall FOIA requests received by CBER began to increase. In fiscal year 2019, CBER received 391 FOIA requests, and in fiscal year 2020, CBER received 399. By fiscal year 2021, CBER began to receive annual requests exceeding 500 (509 in fiscal year 2021 and 633 in fiscal year 2022), exacerbated by requests for records related to the COVID-19 global pandemic. Some of these more recent requests collectively seek millions of pages of records.

FOIA administration is an unfunded mandate—that is, it is not a separate "line item" category in legislative appropriations for the agency, and thus FOIA operations must be funded from general budgetary appropriations. See, e.g., DOJ, FOIA Update: FOIA Affected by Budget Constraints, <https://www.justice.gov/oip/blog/foia-update-foia-affected-budget-constraints>. Accordingly, when the agency receives more FOIA requests than usual, it cannot hire more employees with specific FOIA funding to assist with the additional work.

Due to the above mentioned circumstances, it is difficult to provide more specificity than an estimated completion date of at least 2 years from now.

Sarah B. Kotler, J.D.
Director, Division of Freedom of Information
US FDA
301-796-8976

From: Kotler, Sarah
Sent: Tuesday, November 7, 2023 11:34 AM
To: Marc Dudley <mdudley@sirillp.com>
Subject: FW: [EXTERNAL] FOIA Control #2023-7590 [IR#1090]

Hi, Marc. Mike Russ forwarded your email to me. As an initial matter, please note that 5 U.S.C. § 552(a)(7)(B)(ii) does not require agencies to provide an estimated date of completion within 24 hours (or any other specific timeframe).

This request, 2023-7590, is pending with the Center for Biologics (CBER). That office currently has at least 94 open requests from your firm, which accounts for 13% of CBER's 725 open requests. Requests are processed first in, first out based on the date of receipt. I hope this helps give your client a sense of the timing for this request. I will also check with CBER's FOIA staff to see if there's a more specific timeline they can provide.

Sincerely,

Sarah Kotler

From: Marc Dudley <mdudley@sirillp.com>
Sent: Tuesday, November 7, 2023 11:07 AM
To: Russ, Wilson <Wilson.Russ@fda.hhs.gov>
Cc: S&G Information Request Staff <foia@sirillp.com>
Subject: [EXTERNAL] FOIA Control #2023-7590 [IR#1090]

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Good morning, Mr. Russ:

Please provide us with an estimated date of completion for this request pursuant to 5 U.S.C. § 552(a)(7)(B)(ii). Be advised that the client has directed us to commence litigation if we do not receive an estimated date of completion for this request within 24 hours.

Thank you for your time and attention to this matter.

Marc A. Dudley, Attorney

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