



September 27, 2022

Siri & Glimstad LLP
200 PARK AVE FL17
17TH FLOOR
New York, NY 10166

In reply refer to file: 2021-4111 (IR#0515) & 2021-4112 (IR#0514)

Dear Ms. Brehm,

This letter is in reply to your Freedom of Information Act (FOIA) requests 2021-4111(IR#0515) seeking “All documents containing FDA’s policies, procedures, and protocols for identifying individual VAERS Reports that need a rapid response and all documents concerning investigation and/or follow-up of same” and 2021-4112 (IR#0514) seeking “All documents identifying, discussing, or following-up on individual VAERS reports that need a rapid response, dated between January 1, 2020 and present date within the Office of Biostatistics and Epidemiology.” Both FOIA requests are dated June 23, 2021 and were received in the Center for Biologics Evaluation and Research on June 24, 2021.

After a thorough and diligent investigation, a search of our records did not locate any documents responsive to your request.

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

Please clearly mark both the envelope and your letter “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 Sarah Kotler at 301-796-8976.

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 not satisfied with any aspect of the processing and handling of this request, please contact:

Ms. Suzann Burk
Director, Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)
20903 New Hampshire Avenue
E-mail: suzann.burk@fda.hhs.gov
Direct Phone: 240-402-8028
Main Phone: 240-402-7800

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
Fax: 202-741-5769
E-mail: ogis@nara.gov

.If you have any questions or if I can be of further assistance, please let me know by referencing the above file number. You can contact me by phone at 240-402-8001 or by e-mail at Elizabeth.Sly@fda.hhs.gov .

Sincerely,

Elizabeth A.
Sly -S

Digitally signed by
Elizabeth A. Sly -S
Date: 2022.09.27 14:34:41
-04'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom Information Branch