

September 30, 2024

Edward Berkovich



In reply refer to file: FDA FOIA # 2023-7653 (Corresponding to CDC FOIA #23-00756-FOIA)

Dear Mr. Berkovich,

This is in reply to your Freedom of Information Act request in which you requested “emails sent by and received by Dr. Rochelle P. Walensky, Sherri A. Berger, and Kevin Griffis (all of whom are CDC personnel) on dates beginning February 1, 2021 through May 31, 2021, containing the word myocarditis.”

Your request was referred, in part, to the U.S. Food and Drug Administration (FDA) from The Centers for Disease Control and Prevention (CDC) for direct response (10 pages total). Your request was received in the Center for Biologics Evaluation and Research on September 1, 2023.

Enclosed are the 10 pages referred to the FDA from the CDC in response to your request.

Regarding FDA equities in the responsive records, we have withheld portions of pages under Exemption (b)(5), 5 U.S.C. § 552(b)(5). That exemption permits the withholding of inter-and intra-agency records which are predecisional, and in this case includes documentation of the deliberative process privilege. Disclosure of such material would inhibit the open and candid expression of such views in similar future deliberations and have a detrimental effort on our decision-making process.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 552(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public’s right to disclosure against the individual’s right to privacy.

In determining to withhold such information, FDA considered 5 U.S.C. § 552(a)(8)(i), when applicable, and whether FDA reasonably foresees that disclosure of such information would harm an interest protected by the relevant exemption(s) and whether disclosure is prohibited by law.

In accordance with 45 CFR § 5.61 and 21 CFR § 20.41(b)(5), you have the right to appeal this determination. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency’s adverse determination should be reconsidered. 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, or emailed within 90 days from the date of this response to FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter “FDA Freedom of Information Act Appeal.” Items arriving or delivered after 5 p.m. Eastern Time will be deemed received on the next workday. 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 Charis Wilson at 240-402-9116.

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)
10903 New Hampshire Avenue
Building 71, Room 3126
Silver Spring, MD 20993-0002
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

Regarding CDC equities in the responsive records, please note that certain portions have been redacted under Exemptions (b)(5), 5 U.S.C. §552(b)(5). If you are not satisfied with these exemptions, you may administratively appeal CDC's withholdings to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services via the Department's online portal at <https://requests.publiclink.hhs.gov/App/Index.aspx>. The appeal must be electronically transmitted within 90 days from the date of this letter.

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 [REDACTED] or by e-mail at [REDACTED].

Sincerely,

Elizabeth [REDACTED]-S [REDACTED]

Elizabeth [REDACTED]
Chief, Access Litigation and Freedom Information Branch