June 13, 2024

John Davidson
Magic Feathers Corp.
[redacted]

In reply refer to file: 2022-5791

Dear Mr. Davidson,

This is in reply to your Freedom of Information Act request in which you requested “all emails or correspondence (with attachments if applicable) containing any of the words "Coxiella", "Burnetii" or "Q fever" to, from or cc’ing any of the following people: Janet Woodcock (Janet.Woodcock@fda.hhs.gov) Peter Marks (Peter.Marks@fda.hhs.gov) Celia Witten (celia.witten@fda.hhs.gov) Steven Hahn Scott Gottlieb Robert Califf Doran Fink (doran.fink@fda.hhs.gov) Jerry Weir Sudhakar B. Pharm. Ph.D. Hui-Lee Wong Ph.D. Rachel Zhang, M.D. Atreya, Prabhakara, Ph.D. Paydar, Sussan, Ph.D. Lisa Wheeler Karen Thomas Joanne Lipkind, M.S. Levy Ofer Michael Nelson Melinda Wharton Mark Sawyer Jeannette Lee James Hildreth Herman Cody Meissner Arthur Reingold Hana El Sahly Eric J. Rubin Paul Offit Paula Annunziato Amanda Cohn Adam Berger Arnold Monto.” Your request was received in the Center for Biologics Evaluation and Research (CBER) on August 9, 2022.

In an e-mail dated August 12, 2022, you confirmed a search within the e-mail inboxes of the following custodians would satisfy CBER’s portion of your request: Peter Marks, Doran Fink, Jerry Weir, Hui-Lee Wong, Rachel Zhang, Prabhakara Atreya, Sussan Paydar, Lisa Wheeler, Karen Thomas, and Joanne Lipkind. In addition, in an e-mail dated August 16, 2022, you confirmed that the scope of the e-mail search for your request is not related to a particular product and is just in regards to the keywords identified in your original request. Lastly, during a telephone conversation on May 19, 2023, you agreed to have Lisa Wheeler’s name removed as a custodian for the records search.

Enclosed are the records located in CBER’s search in response to your request. Please note that you may receive response(s) from other FDA component(s).

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 552(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

In addition, 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

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: 2024.06.13 09:49:25 -04'00'

Elizabeth Sly, M.S.
Chief, Access Litigation and Freedom Information Branch