U.S. FOOD & DRUG ADMINISTRATION

April 2, 2020

Molly Zurflueh, Esq.
1278 Glenneyre Street, Suite 262
Laguna Beach, CA 92651

In reply refer to file: F20-2706

Dear Ms. Zurflueh,

This letter is in reply to your Freedom of Information Act request dated March 24, 2020, in which you requested "A copy of the report for each clinical trial the FDA relied upon to approve each influenza vaccine for use during pregnancy." Your request was received in the Center for Biologics Evaluation and Research (CBER) on April 2, 2020.

CBER interprets your request to pertain to clinical studies that were designed to specifically administer inactivated influenza vaccines to pregnant women. **If this is not what you are seeking**, **please feel free to reach out with any clarification that you would like to provide**. Clinical studies for inactivated influenza vaccines did not specifically enroll pregnant women. Inactivated influenza vaccines licensed for use in an age range that includes women of childbearing age are not contraindicated for use in pregnant women and therefore, may be administered to pregnant women. Studies for these vaccines were not designed to specifically enroll pregnant women, therefore, we have no records 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:

Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
Email: FOIARequest@PSC.hhs.gov

Please clearly mark both the envelope and your letter or email "**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:

Beth Brockner Ryan, Branch Chief
Center for Biologics Evaluation and Research (CBER)
Access Litigation and Freedom of Information Branch
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 71, Room 1114
Silver Spring, MD 20993-0002
E-mail: beth.brocknerryan@fda.hhs.gov
Main Line 240-402-7800
FOI Line 240-402-8008

You also have the right to contact:

FDA FOIA Public Liaison
Office of the Executive Secretariat
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 I can be of further assistance, please let me know by referencing the above file number. You can reach me by phone at 240-402-8008 or by e-mail at Beth.BrocknerRyan@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2020.04.02 13:41:01 -04'00'

Beth Brockner Ryan, Branch Chief
Access Litigation and Freedom of Information Branch
Center for Biologics Evaluation and Research
Food and Drug Administration