U.S. FOOD & DRUG ADMINISTRATION

November 9, 2018

Siri & Glimstad LLP
Aaron Siri, Esq.
200 Park Ave. 17th Floor
New York, NY 101066

In reply refer to files: **2018-7617 and 2018-8223**

Dear Mr. Siri,

This letter is in reply to your Freedom of Information Act (FOIA) requests: 2018-7617 dated September 19, 2018 and 2018-8223 dated September 21, 2018, in which you requested "a copy of the report for each clinical trial relied upon by the FDA when approving the Tdap vaccine Boostrix or Adacel for pregnant women" and "a copy of the report for each clinical trial relied upon by the FDA when approving for use by pregnant women any influenza vaccine currently approved by the FDA" respectively.

In a telephone conversation with Beth Brockner-Ryan on October 25, 2018, you clarified your request (2018-8223) stating that you did not want any records pertaining to High-Dose influenza vaccines or the Intranasal influenza vaccine.

Additionally, in an October 26, 2018 e-mail you stated: "This shall serve as a response to your question of yesterday regarding ICAN's requests 2018-7617 and 2018-8223. These requests sought the clinical trials relied upon by the FDA prior to approving any currently licensed influenza vaccine or Tdap vaccine for use in pregnant women as an indicated use. You asked if ICAN was willing to modify this request. ICAN's response is negative. They would like, as requested, the clinical trials relied upon by the FDA prior to approving any currently licensed influenza vaccine or Tdap vaccine for use in pregnant women as an indicated use." CBER interprets your requests to pertain to clinical studies that were designed to specifically administer inactivated influenza vaccines and TdaP vaccines to pregnant women. Clinical studies for TdaP and inactivated influenza vaccines did not specifically enroll pregnant women. TdaP and 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. We have no records responsive to your requests.

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 requests and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Ms. Catherine Teti
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

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:

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

If I can be of further assistance, please let me know by referencing the above file numbers. You can reach me by phone at 240-402-8079 or by e-mail at John.Hyder@fda.hhs.gov.

Sincerely,

John M. Hyder -S

Digitally signed by John M. Hyder -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John M. Hyder -S, 0.9.2342.19200300.100.1.1=2000432462
Date: 2018.11.09 13:01:07 -05'00'

John Matthew Hyder, Consumer Safety Officer
Access Litigation and Freedom of Information Branch
Center for Biologics Evaluation and Research
Food and Drug Administration