U.S. FOOD & DRUG ADMINISTRATION

September 29, 2021

Gabrielle Palmer
Informed Consent Action Network
Siri & Glimstad LLP
200 Park Avenue, 17th Floor
New York, NY 10166

In reply refer to file: 2021-6184 (IR#0558)

Dear Ms. Palmer,

This is in reply to your Freedom of Information Act request dated September 14, 2021, in which you requested "a copy of page 8 of the document available at https://www.fda.gov/media/151733/download, without any redaction of the ingredients listed at the top of that page." Your request was received in the Center for Biologics Evaluation and Research on September 20, 2021.

Enclosed please find 2 pages from the document found at the link you provided (the Summary Basis for Regulatory Action for BLA STN 125742/0), that contain Table 2 titled "*Composition of COMIRNATY Multiple Dose Vial*".

We interpret your request, "the ingredients listed at the top of that page," to be a request for the content in Table 2 of the Summary Basis for Regulatory Action (SBRA). In order to provide you with all of Table 2, we are providing you with the 2 enclosed pages. Please note that while there are some redactions on the 2 provided pages, there are no redactions to Table 2.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 522(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.

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 Katherine Uhl at 301-796-8975.

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

Ms. Beth Brockner-Ryan
Chief, Access Litigation and Freedom of Information Branch
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
E-mail: beth.brocknerryan@fda.hhs.gov
Direct Phone: 240-402-8026
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 we can be of further assistance, please let us know by referencing the above file number. You can contact Elizabeth Sly by phone at 240-402-8001 or by e-mail at Elizabeth.Sly@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: 2021.09.29 13:34:45 -04'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch