EXHIBIT C

From: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
Sent: Thursday, July 28, 2022 10:52 AM
To: Hughes, Paul <Phughes@mwe.com>
Subject: FDA FOIA 2022-4337

[External Email]
Dear Requester:

The Food and Drug Administration (FDA) has completed processing your request for "Internal communications involving specified custodians relating to any aspect of Vanda's tradipitant development program" under the Freedom of Information Act (FOIA).

We are denying your entire request. Specifically, we are denying internal communications.

The following exemption(s) of FOIA, 5 U.S.C. 552, is the authority for denying you access to the non-disclosable material: Exemption (b)5 Certain interagency and intra-agency communications. We have included citations to the FOIA and FDA's regulations for your information.

Section 5.31 (e) of the implementing regulations of the Department of Health and Human Services (DHHS) is applicable to this denial. The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

The following sections of the implementing regulations of FDA and reason(s) applicable to this denial are contained in the CFR, Title 21

- Section 20.62 Intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable. The information also contains a discussion of legal and policy matters and fall within the attorney work product and attorney-client privileges as enunciated by the Supreme Court in National Labor Relations Board v. Sears, Roebuck & Co., 421 U.S. 132 (1975) of the implementing regulations of FDA and reason(s) applicable to this denial
- Section 20.105, 20.106

FDA's Regulations at CFR Part 20 are available at:
http:www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html

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 Sarah Kotler at 301-796-8976. 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 as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769; e-mail at ogis@nara.gov.

Sincerely yours,

Sarah Kotler
Director
Division of Freedom of Information