EXHIBIT B

U.S. FOOD & DRUG ADMINISTRATION

October 10, 2023

MCDERMOTT WILL & EMERY
PAUL W. HUGHES
500 North Capitol Street, NW
Washington DC 20001 US

In Reply refer to
FOIA Control #:
2023-8841

Requester reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

With respect to identified custodians, Vanda requests any correspondence or communications (including e-mails, letters, facsimiles, direct or instant messages, and any other form of correspondence, inclusive of any minutes, records, notes, or memorandum regarding the same) with any individual or entity outside of FDA relating to any aspect of Vanda's development programs, applications, approvals, or otherwise concerning the drug Fanapt® (also known as iloperidone), including but not limited to documents concerning NDA No. 022192 and any supplemental New Drug Applications deriving from that NDA.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8)(i). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm. PLEASE NOTE: HOURLY RATES FOR SEARCH AND REVIEW INCREASED FOR ALL REQUESTS RECEIVED ON OR AFTER JUNE 1, 2023.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Pamela A. Prue, Information Technician, at (301) 796-8984 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director