

EXHIBIT A



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March 31, 2023

VIA ONLINE PORTAL

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Freedom of Information Act (FOIA) request

To whom it may concern:

The Center for Drug Evaluation and Research (CDER) develops standard operating procedures (SOPs) “as supplements to their” Manual of Policies and Procedures. *See MAPP 4001.1 Rev. 1: Developing, Issuing, and Maintaining Standard Operating Procedures for CDER*, (Feb. 1, 2023), perma.cc/JPC3-VK8B. The Department of Health and Human Services has publicly acknowledged that it and its subagencies (such as FDA) maintain SOPs concerning requests under the Freedom of Information Act (FOIA). *See 2021 Chief FOIA Officer Report: Section II: Steps Taken to Ensure that Your Agency Has an Effective System in Place for Responding to Requests*, HHS (Mar. 10, 2021), perma.cc/74UH-JJXB.

Pursuant to 5 U.S.C. § 552 and 21 C.F.R. § 20.40, I write to request the following records on behalf of Vanda Pharmaceuticals Inc:

- Any CDER SOPs, guidance, procedures, or similar records related to the requirements for or processing, prioritization, triage, assignment to a particular “track” or “queue,” or categorization of FOIA requests.

My postal address is below, and telephone number is identified above. I will be responsible for payment of any fees that may be charged. If the anticipated fees will exceed \$25,000 (twenty-five thousand dollars) please contact me. If FDA requires advance payment, please contact me promptly so that we may transfer funds.

I would prefer to receive responses by email if possible. If the responsive documents cannot be emailed, please contact me so that we can make arrangements for production on physical media.

Paul W. Hughes
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Best regards,

A handwritten signature in black ink, appearing to read "Paul W. Hughes". The signature is fluid and cursive, with the first name "Paul" being the most prominent.

Paul W. Hughes
Attorney for Vanda Pharmaceuticals Inc.