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September 26, 2022

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:

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.:

- For purposes of this request, the "custodians" are the following individuals:[1]
    - Dr. Robert Temple, CDER Deputy Center Director for Clinical Science and Senior Advisor in the Immediate Office OF THE Office of New Drugs;
    - Dr. Janet Woodcock, FDA Principal Deputy Commissioner;
    - Dr. Peter Stein, Director of CDER's Office of New Drugs;
    - Dr. Billy Dunn, Director, Office of Neuroscience;
    - Dr. Teresa Buracchio, Director, Division of Neurology;
    - Dr. Tiffany R. Farchione, Director of the Office of Neuroscience – Division of Psychiatry;
    - Dr. Bernard Fischer, Deputy Director;
    - Dr. Martine Solages, Clinical Team Lead;

[1] Please note that titles are supplied for assistance in identifying the individual. Many of these individuals have held various positions at FDA, and our request is for the individuals' communications in the whole, and not limited to any specific position.

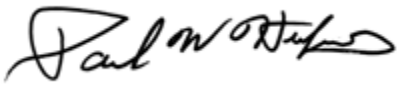
- Dr. Roberta Glass, Clinical Reviewer;
- Luning (Ada) Zhuang, Clinical Pharmacology Team Leader;
- Dr. Juli Tomaino, Medical Team Leader; Deputy Division Director;
- Dr. Patricia Cavazzoni, Director of CDER;
- Dr. Douglass Throckmorton, Director of Regulatory Programs;
- Valerie Magda, Regulatory Project Manager; and
- Elizabeth Jungman, director of CDER's Office of Regulatory Policy.

- With respect to these identified custodians, Vanda requests any correspondence or communications (including e-mails, letters, facsimiles, 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 regarding the drug tasimelteon (trade name Hetlioz®). This includes, but is not limited to, any correspondence regarding Vanda's new drug application (NDA 205677), its subsequent supplemental applications regarding tasimelteon, and all other correspondence or communications mentioning or relating to tasimelteon (also known as Hetlioz).

In responding to this request, please include all documents where the custodian is the sender, recipient (whether principal or secondary), author, or otherwise has custody over the document.

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.

Best regards,



Paul W. Hughes
Attorney for Vanda Pharmaceuticals, Inc.