# EXHIBIT C

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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:

FDA has published a final rule concerning the "Requirements for Submission of Bioequivalence Data" in ANDAs. *See* 74 Fed. Reg. 2849 (Jan. 16, 2009) ("We are revising our regulations to require applicants to submit data on all BE studies, including studies that do not meet passing bioequivalence criteria."); 21 C.F.R. § 314.94(a)(7)(i) ("A complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval. For all other bioequivalence studies conducted on the same drug product formulation[,] . . . the applicant must submit either a complete or summary report.").

FDA has clarified that bioequivalence study results and summaries are available through FOIA. 74 Fed. Reg. 2857 (Jan. 16, 2009) ("Information submitted on passing and nonpassing bioequivalence studies will be available for public release after approval of the application or supplemental application, consistent with FDA's disclosure regulations in 21 CFR part 20 and § 314.430, and with the FOIA."). And the same regulation notes that "in addition to the study results, the applicant's explanations concerning failed studies and the agency's determination and the basis for its determination of bioequivalence will also be publicly available." *Id.*

On December 20, 2022, FDA approved Apotex Corp's ANDA for tasimelteon, No. 211607. 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:

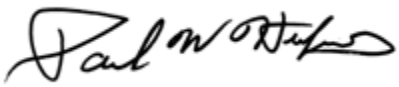
- Any bioequivalence study or dissolution study data, complete study reports, or summary study reports submitted during FDA's consideration of ANDA No. 211607.

- Any explanations submitted by the ANDA applicants concerning any failed studies submitted during FDA's consideration of ANDA No. 211607.

- Any regulatory communications or discipline reviews (excluding bioequivalence reviews) which discuss the ANDA applicants' studies, which FDA produced during its consideration of ANDA Nos. 211607.

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,



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