EXHIBIT D

mwe.com

Paul W. Hughes
Partner
phughes@mwe.com
+1 202 756 8981

August 29, 2022

Director
Office of the Executive Secretariat
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1050
Rockville, MD 20857

Re: FDA Freedom of Information Act Appeal
Request No. 2022-4337

To whom it may concern:

I write on behalf of Vanda Pharmaceuticals, Inc., to appeal the determination by the Food and Drug Administration to deny Vanda's request pursuant to the Freedom of Information Act. Specifically, Vanda requested internal communications involving eleven specified individuals employed by FDA relating to Vanda's tradipitant development program (VLY-696 IND 131545). *See* Ex. A. Vanda's FOIA request was assigned identification number 2022-4337.

On July 28, 2022, FDA notified Vanda by email that FDA believes that certain requested records are exempt from FOIA disclosure under Exemption Five, which covers "inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5); Ex. B at 1. FDA asserts that Exemption Five applies because the documents at issue fall within the deliberative process privilege in addition to the attorney-client privilege and the attorney work product doctrine. *Id.*

It is implausible that every responsive record is covered by one or more of these privileges. At the very least, FOIA obligates FDA to perform a search to determine if there are non-privileged records. It was thus unlawful for FDA to categorically deny Vanda's request.

I. Background.

Vanda is currently developing tradipitant, a drug that has shown exceptional promise to treat severe nausea in gastroparesis patients. In September 2016, Vanda submitted its Investigational New Drug

Application (IND) for tradipitant, which was assigned the IND number 13,1545. The IND included proposals for a variety of human studies to test the safety and efficacy of tradipitant.

In December 2018, FDA imposed a partial clinical hold on tradipitant, preventing Vanda from studying the drug in humans for longer than 3 months until it conducted a 9-month toxicity study in nonrodent animals. Vanda challenged this decision through litigation. *See Vanda Pharmaceuticals, Inc. v. FDA*, No. 19-cv-00301 (D.D.C.).

On March 28, 2019, Vanda submitted a request for Breakthrough designation for tradipitant. FDA denied the request on May 31, 2019. At FDA's suggestion, Vanda submitted a second request for Breakthrough Therapy designation with additional data. FDA denied this request as well. Vanda unsuccessfully appealed through Formal Dispute Resolution under 21 C.F.R. § 10.75.

Vanda submitted a request for Fast Track designation for tradipitant on October 6, 2021. On February 1, 2022—after nearly twice the statutorily mandated timeframe for a decision—FDA denied Fast Track designation for tradipitant. Vanda has repeatedly sought clarification from FDA, and has recently initiated litigation to challenge this denial. *See Vanda Pharmaceuticals, Inc. v. FDA*, No. 22-cv-1432 (D.D.C. 2022).

Vanda submitted a FOIA request to FDA on June 10, 2022, seeking internal communications concerning the tradipitant development program involving any of eleven specified individuals. Specifically, Vanda sought communications involving:

- 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. Julie Beitz, Director of the Office of Immunology and Inflammation;
- Dr. Lisa M. Soule, Associate Director, Division of Gastroenterology and Inborn Errors Products;
- Dr. Juli Tomaino, Medical Team Leader; Deputy Division Director;
- Dr. Jessica Lee, Director, Division of Gastroenterology;
- Maureen Dewey, Senior Regulatory Project Manager;
- Dr. Patricia Cavazzoni, director of CDER;

- Dr. Douglass Throckmorton, director of Regulatory Programs; and
- Elizabeth Jungman, director of CDER's Office of Regulatory Policy.

On July 26, 2022, Vanda was informed that FDA intended to deny the request by a FOIA Branch Chief in a meeting with Paul Hughes. On July 28, 2022, FDA issued a denial by email, signed by Sarah B. Kotler. Ex. B. In the denial letter, FDA asserted that it was entitled to withhold the requested records under FOIA's Exemption 5. *Id.* at 1. The denial letter instructed that Vanda had the right to appeal FDA's determination by letter within 90 days. Vanda thus timely submits this appeal.

II. The Internal Communications Cannot All Be Withheld.

FDA denied Vanda's request in its entirety, asserting that responsive records were covered by Exemption 5. Exemption 5 permits agencies to withhold "inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). In its denial, FDA identified the deliberative process privilege, attorney-client privilege, and attorney work product doctrine as bases for withholding. But the responsive records are not *all* covered by the privileges that FDA asserts. FDA was thus not entitled to categorically deny Vanda's request.

A. The attorney-client privilege and attorney work product doctrine do not apply to all responsive records.

FDA claims that responsive records "contain[] a discussion of legal and policy matters and fall within the attorney work product and attorney-client privileges." Ex. B at 1. Under FOIA, however, "all privileges" are "narrowly construed and limited to those situations in which [their] purposes will be served." *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 862 (D.C. Cir. 1980). It is simply impossible that all of the records responsive to Vanda's requests would fall under either of these privileges.

1. *The attorney-client privilege does not apply to all responsive records.*

The attorney-client privilege "applies only if the person to whom the communication was made is 'a member of the bar of a court' who 'in connection with the communication is acting as a lawyer' and the communication was made 'for the purpose of securing primarily either (i) an opinion on law or (ii) legal services or (iii) assistance in some legal proceeding.'" *Nat'l Sec. Counselors v. CIA*, 960 F. Supp. 2d 101, 193 (D.D.C. 2013) (quoting *In re Lindsey*, 158 F.3d 1263, 1270 (D.C. Cir. 1998)). Moreover, this privilege is "narrowly construed and is limited to those situations in which its purposes will be served"—*i.e.*, when applying the privilege is necessary to "'protect[] . . . disclosures necessary to obtain informed legal advice which might not have been made absent the privilege.'" *Coastal States*, 617 F.2d at 862 (quoting *Fisher v. United States*, 425 U.S. 391, 403 (1976)).

It is implausible that all records responsive to Vanda's request fall under the attorney-client privilege. To begin, Vanda requested communications involving eleven specified individuals. To Vanda's

knowledge, only one of those individuals—Elizabeth Jungman—is an attorney. An attorney did not participate in *all* communications relating to Vanda that did not copy Ms. Jungman. Given that there are no doubt enormous numbers of communications *without* a lawyer, this privilege cannot conceivably shield all correspondence relating to the other 10 custodians requested. *See In re Lindsey*, 158 F.3d at 1270.

Even those records involving Ms. Jungman do not automatically qualify, since it is not clear that she was "acting as a lawyer" "in connection with the communication." *Id.* As Director of CDER's Office of Regulatory Policy, Ms. Jungman "helps oversee the development and implementations of regulations, policies, and procedures" and "advises senior FDA officials in matters impacting policy development and long-range organizational goals." *Elizabeth Jungman, J.D., M.P.H.*, FDA (Oct. 22, 2019), perma.cc/ZNZ3-KJWF. But "consultation with one admitted to the bar but not in that other person's role as a lawyer is not protected" by the attorney-client privilege. *Judicial Watch, Inc., v. Dep't of Homeland Security*, 926 F. Supp. 2d 121, 144-45 (D.D.C. 2013) (quoting *In re Lindsey*, 158 F.3d at 1270). Communications made in Ms. Jungman's policy-oriented role containing "advice on political, strategic, or policy issues" thus "would not be shielded from disclosure by the attorney-client privilege." *Id.*

Even if some responsive communications involved agency counsel, that alone is not enough to trigger the privilege—if it were, any agency could circumvent FOIA by copying a lawyer on every internal communication. Rather, to be privileged, a communication must be made to counsel for the purpose of obtaining legal advice. *See, e.g.*, *Chesapeake Bay Found., Inc. v. U.S. Army Corps of Eng'rs*, 722 F. Supp. 2d 66, 73 (D.D.C. 2010) ("The attorney-client privilege protects from disclosure information 'communicated to or by an attorney as part of a professional relationship in order to provide the [client] with advice on the legal ramifications of its actions.'") (quoting *Mead Data Cent., Inc. v. Dep't of Air Force*, 566 F.2d 242, 253 (D.C. Cir. 1977)); *see also In re Lindsey*, 148 F.3d at 1106.

Vanda's request sought internal communications on a number of specific subjects but encompassed "any internal communications . . . relating to any aspect of Vanda's tradipitant development program." Ex. A. at 1. Many components of the tradipitant development program and application involved purely regulatory and scientific decisions by FDA. There is no reason to believe that *all* communications between FDA officials concerning Vanda's tradipitant development program were to or from counsel for the purpose of obtaining legal advice.

2. *The attorney work product doctrine does not apply to all responsive records*.

FDA's reliance on the attorney work product doctrine is similarly misplaced. The work-product doctrine protects only "'documents and tangible things that are [1] prepared in anticipation of litigation or for trial' [2] by an attorney." *Am. Immigration Council v. U.S. Dep't of Homeland Sec.*, 905 F. Supp. 2d 206, 221 (D.D.C. 2012) (quoting Fed. R. Civ. P. 26(b)(3)). The communications Vanda sought could not possibly categorically satisfy either of these requirements.

As discussed above, Elizabeth Jungman is the only named custodian who is an attorney. Communications from Robert Temple, Janet Woodcock, Peter Stein, Julie Beitz, Lisa M. Soule, Juli

Tomaino, Jessia Lee, Maureen Dewey, Patricia Cavazzoni, and Douglass Throckmorton thus cannot be "prepared . . . by an attorney." *Id.*

Nor is there is any reason to conclude that *all* of Ms. Jungman's communications were "prepared in anticipation of litigation." *Id.* In order to be "in anticipation of litigation," a document must do more than provide "[n]eutral, objective analysis" of the law; instead, it must provide "pointed advice" that "anticipates litigation" by "recommend[ing] 'how to proceed further with specific investigations' or 'advis[ing] the agency of the types of legal challenges likely to be mounted against a proposed program, potential defenses available to the agency, and the likely outcome.'" *Id.* at 221-22 (quoting *Delaney, Migdail & Young, Chartered v. IRS*, 826 F.2d 124, 127 (D.C. Cir. 1987)). Moreover, the lawyer must have a "subjective belief that litigation [is] a real possibility," and that belief must be "objectively reasonable." *In re Sealed Case*, 146 F.3d 881, 884 (D.C. Cir. 1998). Additionally, the work-product privilege ordinarily does not apply until "some articulable claim, likely to lead to litigation" arises. *Coastal States*, 617 F.2d at 865. There is thus no reason to believe that all responsive communications are covered by the work-product doctrine.

B. Not all responsive records are subject to the deliberative process privilege.

Additionally, FDA purported to deny Vanda's request because responsive records were "intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable."[1] The responsive records cannot all be subject to the deliberative process privilege. That privilege protects "agency materials that are *both* pre-decisional *and* deliberative." *Pavement Coatings Tech. Council v. United States Geological Survey*, 2019 WL 7037527, at *4 (D.D.C. Dec. 19, 2019). The deliberative process privilege is highly fact-sensitive such that it should not be categorically invoked. *See Playboy Enterprises, Inc. v. Dep't of Justice*, 677 F.2d 931, 935 (D.C. Cir. 1982) (holding that the "deliberative process privilege is . . . dependent upon the individual document and the role it plays in the administrative process.").

To begin with, the responsive communications are not all predecisional. "Put simply, a pre-decisional record is one 'prepared in order to assist an agency decisionmaker in arriving at his decision.'" *Pavement Coatings Tech. Council v. U.S. Geological Survey*, 995 F.3d 1014, 1021 (D.C. Cir. 2021) (quoting *Petroleum Info Corp. v. U.S. Dep't of the Interior*, 976 F.2d 1429, 1434 (D.C. Cir. 1992)). As a matter of simple logic, a record cannot be predecisional if it *postdates* the relevant agency decision. But nothing in Vanda's request limits its search to records created before relevant agency decisions. By its

[1] The denial also cited 21 C.F.R. § 20.62, which applies to inter- or intra-agency memoranda. To the extent that FDA claims that this regulatory provision permits it to withhold *all* internal communications, it is plainly wrong. As discussed below, and as FDA well knows, Exemption 5 covers "those documents, and *only* those documents that are normally privileged in the civil discovery context." *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 149 (1975) (emphasis added). Thus, to the extent that Section 20.62 would permit withholding of nonprivileged communications, it is inconsistent with the plain text of FOIA and invalid. Similarly, Sections 20.105 and 20.106—which do not immediately appear to be relevant to Vanda's request—are not an independent basis for disclosure beyond the privileges incorporated into Exemption 5.

own terms, for example, the request would reach communications involving any of the specified individuals about FDA's denial of Fast Track status *after* the denial was issued. The same is true for communications involving any past FDA decision relating to tradipitant.

Nor do all responsive records qualify as "deliberative." It is established that "a document is 'deliberative' if it 'makes recommendations or expresses opinions on *legal or policy matters*.'" *Baldwin v. U.S. Dep't of Energy*, 2020 WL 376563, at *3 (D.D.C. 2020) (quoting *Vaughn v. Rosen*, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975)). The privilege protects only records "so candid or personal in nature that public disclosure is likely in the future to stifle honest and frank communication." *Coastal States*, 617 F.2d at 866. It does not cover "non-discretionary, factual, and scientific documents." *Ctr. for Biological Diversity v. United States EPA*, 279 F. Supp. 3d 121, 151 (D.D.C. 2017). Nor can agencies use the deliberative process privilege to withhold "purely factual material." *Quarles v. Department of the Navy*, 893 F.2d 390 (D.C. Cir. 1990).

It is overwhelmingly unlikely that all responsive communications meet this standard. The deliberative process privilege "appl[ies] only to documents that contribute to an ongoing deliberative process within an agency." *Access Reports v. Dep't of Justice*, 926 F.2d 1192, 1195 (D.C. Cir. 1991). Not all relevant communications will be part of any deliberative process, such as communications assigning work or those discussing both deliberative and nondeliberative matters. And responsive communications may well contain only factual information, such as memoranda of meetings or calls. Categorical application of the privilege is especially inappropriate here where the specified individuals are largely high-ranking FDA officials—courts have consistently held that communications "from senior to junior" are far less likely to be deliberative. *Id.*

In sum, FDA cannot claim that responsive records categorically fall within the deliberative process privilege. Indeed, the privilege is necessarily "dependent upon the individual document and the role it plays in the administrative process." *Coastal States*, 617 F.2d at 867. Vanda's request covers records that are certainly not predecisional and not deliberative. The deliberative process privilege would not apply to these communications.[2]

III. FDA Must Perform an Adequate Search for Responsive Documents.

Vanda's request reasonably describes a set of responsive documents and was made in accordance with FDA's published rules. FDA has not suggested otherwise. The Freedom of Information Act is explicit that "upon any [such] request for records" the agency must "make the records promptly available." 5 U.S.C. § 552(a)(3)(A). The D.C. Circuit has explained that FOIA "sets forth the broad outlines of a process

[2] This argument applies at an additional level of granularity, as well: "To justify withholding a document in full, an agency must show with 'reasonable specificity' why the document cannot be further segregated." *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 926 F. Supp. 2d 311, 315 (D.D.C. 2013) (quoting *Johnson v. Exec. Office for U.S. Attorneys*, 310 F.3d 771, 776 (D.C. Cir. 2002)). FDA's "generic declaration that . . . factual content is inextricably intertwined with the basis for withholding and is therefore, not segregable, does not constitute a sufficient explanation of segregability." *Carter, Fullerton & Hayes LLC v. F.T.C.*, 520 F. Supp. 2d 134, 148 (D.D.C. 2007).

for agencies to follow when responding to FOIA requests: first, identify responsive records; second, identify those responsive records or portions of responsive records that are statutorily exempt from disclosure; and third, if necessary and feasible, redact exempt information from the responsive records." *Am. Imm. Laws. Ass'n v. Exec. Office for Imm. Rev.*, 830 F.3d 667, 677 (D.C. Cir. 2016). An agency's FOIA response thus requires, at the very least, a search for responsive records. *See Id.* § 552(a)(3)(C)-(D); *Bigwood v. United States Dep't of Defense*, 132 F. Supp. 3d 124, 135 (D.D.C. 2015) ("The agency must make 'a good faith effort to conduct a search for the requested records, using methods which can be reasonably expected to produce the information requested.'") (quoting *Oglesby v. Dep't of the Army*, 920 F.2d 57, 68 (D.C. Cir. 1990)).

FOIA does not permit an agency to evade an obligation to conduct a search for responsive records simply because it believes some or even most records will be subject to withholding. "The statute does not provide for withholding responsive but non-exempt records" at all. *Am. Imm. Laws. Ass'n*, 830 F.3d at 677. To be sure, courts have recognized that agencies need not perform searches when the agency reliably asserts that responsive records are not, in fact, maintained. *See Whitaker v. Dep't of Com.* 970 F.3d 200, 208 (2d Cir. 2020). But that narrow exception is not applicable here—there is no possibility that FDA does not maintain records of internal communications. And "[i]n the absence of such a showing . . . courts have required agencies to conduct a search." *Department of Justice Guide to the Freedom of Information Act*, DOJ 58 (Aug. 20, 2021), perma.cc/SMM3-6K4Y.

Based on FDA's response, it appears that the agency has refused to perform a search under the theory that responsive records fall under Exemption 5. This is not a permissible basis on which to categorically deny an otherwise valid request under FOIA.[3] FDA must therefore perform a search for responsive records.

Vanda acknowledges, of course, that *some* responsive communications may fall within one or more of Exemption 5's privileges. But as described above, it is simply impossible that *all* responsive communications can be properly withheld. At minimum, FDA must disclose to Vanda now the information that the agency would have to provide in a *Vaughn* index if the dispute reached litigation.[4] This information includes the names, dates, authors, recipients, and page counts of the requested communications; the reason and statutory authority for withholding each; and the number of pages in each communication containing privileged information. *See, e.g.*, *Judicial Watch, Inc. v. FDA*, 440 F.3d 141, 146 (D.C. Cir. 2006) (describing previous FDA *Vaughn* index that furnished all of this information). FDA

[3] Indeed, FOIA specifically provides that "[i]n denying a request for records, in whole or in part, an agency shall make a reasonable effort to estimate the volume of any requested matter the provision of which is denied, and shall provide any such estimate to the person making the request." 5 U.S.C. § 552(a)(6)(F).

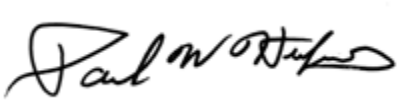
[4] "'*Vaughn* Index' is a term derived from *Vaughn v. Rosen*, 484 F.2d 820 (1973). The 'Index' usually consists of a detailed affidavit, the purpose of which is to 'permit the court system effectively and efficiently to evaluate the factual nature of disputed information.'" *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 149 n.2 (1989) (parallel citations omitted). Without such an index, a reviewing court cannot evaluate whether the agency has met its burden to show that it has withheld information appropriately.

cannot assert that *this* information is subject to a FOIA exemption; indeed, the purpose of a *Vaughn* index is to evaluate FDA's invocation of FOIA exemptions.

* * *

Thank you for your attention to this matter. If you wish to discuss this appeal, I can be reached at (202) 756-8981 or phughes@mwe.com.

Sincerely,



Paul W. Hughes