IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDA PHARMACEUTICALS, INC.,
2200 Pennsylvania Avenue NW
Suite 300E
Washington, DC 20037

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD 20993

Defendant.

Civ. No. 1:22-cv-938

COMPLAINT FOR INJUNCTIVE RELIEF

Plaintiff Vanda Pharmaceuticals, Inc. ("Vanda") brings this Complaint against Defendant Food and Drug Administration and alleges as follows:

NATURE OF THE ACTION

1. Plaintiff Vanda Pharmaceuticals, Inc., is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high-priority unmet medical needs, in order to improve the lives of patients.

2. Vanda brings this action to compel Defendant Food and Drug Administration ("FDA") to produce records to Vanda as required by the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552.

3. In order to obtain marketing approval for a new drug, a drug sponsor must submit to FDA a New Drug Application ("NDA"). To add a new indication to a drug already on the

market, a drug sponsor must submit to FDA a Supplemental New Drug Application ("sNDA"). In response to receipt of an NDA or sNDA, FDA typically prepares a Medical Review (also called a Clinical Review) and a Statistical Review (the "Reviews") as part of a Multi-Discipline Review package.

4. A Medical Review reviews the strength of the clinical evidence submitted in support of the application; a Statistical Review reviews the statistical validity of the findings of the clinical studies performed by the sponsor. These Reviews are usually the most critical evidence used by FDA to determine what action to take on an NDA or an sNDA.

5. If FDA approves the drug application, FDA publishes these Reviews on its website, as part of a Drug Approval Package. *See infra* ¶¶ 32, 64, 71-72. If FDA disapproves the drug application, FDA will produce these reviews in the administrative record if a drug sponsor sues FDA to contest the lawfulness of the disapproval decision. But, if FDA disapproves a drug application and the drug sponsor does not challenge that result in court, FDA has adopted a policy of refusing to provide the sponsor copies of the Reviews that caused the denial of the application.

6. Relevant here, Vanda markets Hetlioz® (tasimelteon). Hetlioz® is indicated for the treatment of Non-24 Sleep-Wake Disorder, a circadian rhythm disorder. Vanda submitted to FDA an sNDA seeking to expand its label for Hetlioz® to include an indication for the treatment of Jet Lag Disorder, which is also a circadian rhythm sleep-wake disorder.

7. On August 16, 2019, FDA issued a complete response letter ("CRL"), denying Vanda's sNDA. In denying Vanda's sNDA, FDA did not provide any of the detailed analysis that is contained in the Reviews, and it supplied no reference to the underlying data.

8. Vanda then filed a FOIA request, asking FDA to provide it the Medical Review and Statistical Review that resulted in the complete response letter.

9. FDA denied Vanda's FOIA request, and Vanda timely appealed that denial through the requisite administrative appeal process.

10. On appeal, FDA admitted that the Reviews are not covered by the attorney-client or work-product privileges but nonetheless denied Vanda's appeal based on the deliberative process privilege, citing 5 U.S.C. § 552(b)(5), FOIA's Exemption 5.

11. The Court should grant injunctive relief directing FDA to produce the requested Reviews to Vanda immediately, because Exemption 5 of FOIA does not apply to the documents Vanda seeks. The deliberative process privilege does not apply for two independent reasons: The Reviews are factual in nature rather than deliberative and, further, the Reviews constitute an essential component of FDA's final decision. The Agency was therefore incorrect to assert that the documents are covered by FOIA Exemption 5.

12. Not only does Vanda have a legal right to receive copies of the Reviews under FOIA's clear mandate, but providing drug sponsors this information is essential to further scientific inquiry. When sponsors, like Vanda here, invest substantial sums investigating new products or new uses for existing products, they must understand the basis for adverse actions taken by FDA. Disclosure of such information to the sponsor enables the sponsor to determine whether to continue pursuing further development efforts or to abandon the product or indication.

13. Further, providing sponsors this information is necessary to enable a drug sponsor to understand if FDA's decision-making is accurate. Sponsors like Vanda cannot meaningfully respond to adverse actions taken by FDA when the agency refuses to supply the sponsor the most critical factual information it relies upon in rendering an adverse decision. At present, Vanda has no way of knowing whether the adverse action FDA took was the product of objective error, such as a miscalculation. By failing to provide Vanda the Reviews, Vanda cannot independently

evaluate or verify the conclusions FDA has reached—conclusions which immediately and substantially injure Vanda.

14. In all, disclosure of this information to drug sponsors—as is plainly required by FOIA—fosters drug development, which ultimately benefits the public. And it ensures agency accountability, enabling drug sponsors to review the agency's factual conclusions. Absent such disclosure, the ability of drug sponsors to engage in meaningful dialogue with the agency is restricted, if not outright eliminated. FDA's apparent programmatic decision to deprive sponsors of this crucial information stifles innovation, precluding new therapeutics from reaching the market and treating patients with unmet medical needs. Moreover, FDA's refusal to disclose this information to drug sponsors inappropriately shields the agency's administrative conclusions from independent scrutiny.

15. Against this backdrop, it is little surprise that academic commentators—including leading scholars and former FDA officials—have called upon FDA to enhance transparency. In 2017, several commentators published a "Blueprint for Transparency at the U.S. Food and Drug Administration," calling on FDA to more regularly disclose crucial information. *See Symposium: Blueprint for Transparency at the U.S. Food and Drug Administration*, J. L., Med. & Ethics, Winter 2017 (Anna L. Davis et al., eds.).

16. In particular, one recommendation offered was that "FDA should make public its clinical and statistical reviews of products not approved." Joshua M. Sharfstein et al., *Blueprint for Transparency at the U.S. Food and Drug Administration*: *Recommendations to Advance the Development of Safe and Effective Medical Products*, 45 J. L., Med. & Ethics 7, 9 (2017).

17. Even FDA acknowledges, at least in broad terms, the need to enhance its disclosure of information. FDA launched the "FDA Transparency Initiative," specifically designed to

"increase[e] the transparency of FDA operations and decision-making" as it relates to regulated industry. *See* FDA Transparency Initiative Overview, https://perma.cc/2AAD-6UVN.

18. It is deeply ironic that FDA is actively seeking to enhance transparency with regulated industry—and leading commentators underscore that providing drug sponsors the Reviews at issue here is of the utmost importance—yet FDA refuses to provide Vanda the Reviews of its own product in response to a lawful FOIA request.

19. It is critical to the transparency of agency action, along with the advancement of medical research, for FDA to provide these materials to drug sponsors. Not only does FDA have a legal obligation under FOIA to disclose to Vanda the contents of the Medical and Statistical Reviews it prepared regarding Hetlioz®, but doing so is necessary to achieve meaningful communications between regulator and drug sponsor, which ultimately accrues to the benefit of patients who suffer from conditions that could be treated through new therapeutics.

PARTIES

20. Vanda is incorporated in Delaware and maintains its principal place of business in Washington, DC. Vanda manufactures Hetlioz® (tasimelteon), a prescription drug approved by FDA for sale in the United States.

21. Defendant Food and Drug Administration ("FDA") is an agency of the United States government within the Department of Health and Human Services, with its principal office at 10903 New Hampshire Avenue, Silver Spring, MD.

JURISDICTION AND VENUE

22. This action seeks injunctive relief under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552.

23. This Court has subject matter jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B). Subject matter jurisdiction is also proper under 28 U.S.C. § 1331 because the cause of action asserted arises under the laws of the United States.

24. Venue in this court is appropriate pursuant to 5 U.S.C. § 552(a)(4)(B).

25. Vanda has exhausted its administrative remedies by appealing FDA's denial of its request. The FDA's Appeal Response stated that it "constitutes the final decision of the Department regarding [the] appeal." Ex. E, at 5.

REGULATORY BACKGROUND

A. FDA's Role in Approving New Drugs

26. The Federal Food, Drug, and Cosmetic Act ("FDCA") makes it unlawful to "introduce or deliver for introduction into interstate commerce any new drug" unless FDA has approved a new drug application for that drug. 21 U.S.C. § 355(a).

27. An NDA must include, among other things, information sufficient to show "whether or not such drug is safe for use and whether such drug is effective in use" and "specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). FDA may decline to approve an NDA on certain grounds enumerated in the FDCA, including (1) that the NDA does not include "adequate tests . . . to show whether or not such drug is safe for use" and (2) "a lack of substantial evidence that the drug will have the effect it purports or is represented to have." *Id.* § 355(d). If none of the statutory grounds for rejecting the NDA applies, FDA "shall" approve the NDA. *Id.*

28. Once FDA has approved an NDA for a new drug, the manufacturer may lawfully market the drug for the use specified in the NDA (in technical terms, the "indication"), which also appears on the label approved as part of the NDA.

29. If a manufacturer wishes to amend an NDA after it has been approved, it can do so by submitting a supplemental new drug application ("sNDA"). *See* 21 C.F.R. § 314.70. For supplements that make "major changes" to an NDA, FDA's prior approval is required before the change can go into effect. *Id.* § 314.70(b).

30. According to FDA's regulations, one such "major change" requiring prior approval is a change in a drug's label identifying a new use for the drug. 21 C.F.R. § 314.70(b)(2)(v)(A); *see also* Ctr. for Drug Evaluation & Research, FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA* 24 (Apr. 2004) (explaining that "labeling changes associated with new indications and usage" require FDA's prior approval).

31. When a drug sponsor submits an NDA or an sNDA, FDA scientists and statisticians prepare memoranda to arrive at certain factual conclusions. A Medical Review typically reviews the strength of the clinical evidence submitted in support of the application; a Statistical Review reviews the statistical validity of the findings of the clinical studies performed by the sponsor.

32. These Reviews are often *the* most critical evidence used by FDA to determine what action to take on an NDA or an sNDA. As noted above, if FDA approves the drug application, the agency then publishes these Reviews on its website as part of the Drug Approval Package. If FDA disapproves the drug application, FDA will produce these reviews in the administrative record *if* a drug sponsor sues FDA, claiming that the disapproval decision was unlawful. But, if FDA disapproves a drug application and the drug sponsor does not challenge that result in court, FDA has adopted a policy of refusing to provide the sponsor with the Reviews that caused the denial of the application.

B. Vanda's sNDA for Hetlioz®

33. Hetlioz® (tasimelteon) is among a class of drugs known as melatonin receptor agonists, which bind to and activate receptors in the brain for melatonin, a hormone that regulates the sleep cycle.

34. Vanda licensed tasimelteon from Bristol-Myers Squibb in 2004. In 2014, after years of development work and clinical trials, FDA approved tasimelteon to treat non-24-hour sleep-wake disorder ("Non-24"), a condition in which an individual's circadian rhythms become misaligned with the 24-hour day.

35. Since 2014, Vanda has marketed tasimelteon under the brand name Hetlioz®.

36. Jet Lag Disorder is an acute circadian rhythm disorder affecting individuals who travel rapidly across multiple time zones.

37. Vanda has conducted several clinical trials and studies to examine whether tasimelteon may be an effective treatment for Jet Lag Disorder.

38. For example, the JET5 study in 2009 found that tasimelteon "improved sleep initiation and maintenance" compared with a placebo, leading the authors to conclude that the drug "may have therapeutic potential" to treat Jet Lag Disorder. Shantha Rajaratnam et al., *Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomised controlled multicentre trials*, 373 The Lancet 482, 482 (2009).

39. Similarly, the JET8 study, recently published in a peer-reviewed journal, concluded that "[a] single dose of tasimelteon improves the primary symptoms of JLD [Jet Lag Disorder], including nighttime insomnia and next day functioning among participants in a laboratory model of JLD simulating eastward trans-meridian travel by inducing an 8-h phase advance of the sleep-wake cycle." Christos M. Polymeropoulos, et al., *Efficacy of Tasimelteon (Hetlioz) In the*

Treatment of Jet Lag Disorder Evaluated in 8-h Phase Advance Model, Frontiers in Neurology (July 9, 2020).

40. In October 2018, Vanda filed an sNDA with FDA, seeking approval to market Hetlioz® for the treatment of Jet Lag Disorder.

41. On August 16, 2019, FDA issued a Complete Response Letter (CRL) in which it declined to accept the sNDA or otherwise approve Hetlioz® for treatment of Jet Lag Disorder.

42. FDA's decision to issue the CRL plainly relies upon the Review materials that FDA scientists or statisticians prepared in response to Vanda's sNDA.

43. It is imperative that Vanda have access to these materials, for multiple reasons. First, Vanda requires this information to thoroughly understand the summary and conclusory statements provided by FDA in the CRL. The Reviews span dozens—and more likely hundreds—of pages of scientific information and factual conclusions and calculations. Without seeing the specific information, Vanda cannot understand whether and how to adapt its development program.

44. Second, Vanda cannot determine whether FDA's conclusions are the product of factual error.

45. FOIA, however, does not tolerate such closed-door decisionmaking. When an agency takes a significant, adverse action against a regulated party, that party has a legal right to know the factual conclusions supporting the agency's action.

C. Vanda's FOIA Request

46. Vanda seeks to understand the factual conclusions FDA has reached and that underlie its actions. If those factual conclusions rest on scientific or statistical error, Vanda must have that knowledge so it can respond to these errors and correct the record. Alternatively, if

FDA's Reviews are correct, Vanda needs that information too, so it can understand whether and how to proceed with its development program.

47. On Monday, December 2, 2019, Vanda submitted a FOIA request to FDA seeking the Medical Review and Statistical Review that FDA generated during its consideration of the sNDA. *See* Ex. A.

48. FOIA requires an agency, after receiving a "request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, [to] make the records promptly available" to the requestor. 5 U.S.C. § 552(a)(3)(A).

49. The agency must "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any [proper FOIA] request whether to comply with such request and shall immediately notify the person making such request of . . . such determination and the reasons therefor." 5 U.S.C. § 552(a)(6)(A).

50. FDA did not satisfy this deadline. The agency notified Vanda by letter (Ex. B) that the Reviews would be withheld under Exemption 5 on the purported ground that they are covered by the deliberative process, attorney-client, and work-product privileges. That letter, however, was dated January 15, 2020, and Vanda did not receive it until January 21, 2020.

51. On January 28, 2020, Vanda appealed FDA's decision to the Department of Health and Human Services' Chief FOIA Officer, in accordance with FDA regulations. Ex. C. The Chief FOIA Officer acknowledged receipt of Vanda's appeal by letter dated January 30, 2020. Ex. D.

52. Under FOIA, the agency was required to "make a determination with respect to [the] appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal." 5 U.S.C. § 552(a)(6)(A)(ii).

53. This 20-day period could be extended, in "unusual circumstances," by no more than ten additional business days. 5 U.S.C. § 552(a)(6)(B)(i). The Chief FOIA Officer's letter indicated that the agency intended to claim an extension of its deadline to decide the appeal based on "unusual circumstances."

54. On May 13, 2021—more than a year after receiving Vanda's appeal letter—the agency's Chief FOIA Officer upheld FDA's decision to withhold the Reviews. The agency conceded that the Reviews were not protected by the attorney-client or work-product privileges. Ex. E at 1 n.2. Nevertheless, it concluded that they were covered by the deliberative process privilege, and that they could therefore be withheld under FOIA's Exemption 5.

FDA'S WITHHOLDING OF THE REVIEWS IS UNLAWFUL

A. The Requested Reviews Are Subject to FOIA

55. FDA's claim that Exemption 5 applies to the requested Reviews is incorrect. Both documents are subject to FOIA.

56. FOIA's general requirement of public access to information is qualified by a limited number of exemptions. One of these exemptions, Exemption 5, excludes from FOIA's coverage "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).

57. Exemption 5 thus covers documents that would, in litigation, be protected from disclosure by the attorney-client privilege, the attorney work-product doctrine, or—as relevant here—the deliberative process privilege. *See, e.g.*, *Pies v. U.S. Internal Revenue Serv.*, 668 F.2d 1350, 1352 (D.C. Cir. 1981).

58. "To qualify for withholding under [the deliberative process privilege], information must be both 'predecisional' and 'deliberative.'" *Petroleum Info. Corp. v. U.S. Dep't of the*

Interior, 976 F.2d 1429, 1434 (D.C. Cir. 1992); *accord Protect Democracy Project, Inc. v. U.S. DHHS*, No. 17-712, 2021 WL 4148312, at *3 (D.D.C. Sept. 13, 2021).

59. "For a record to qualify as pre-decisional, it must be created *before* the relevant agency policy or decision, and must have been 'prepared in order to assist an agency decisionmaker in arriving at his decision.'" *Pavement Coatings Tech. Council v. United States Geological Survey*, 2019 WL 7037527, at *4 (D.D.C. Dec. 19, 2019) (quoting *Petroleum Info. Corp.*, 976 F.2d at 1434). Moreover, "records can lose their pre-decisional status if they are formally or informally adopted as the official agency position on an issue, or if they are used in agency dealings with the public." *Id.* (citing *Hall & Assocs. LLC v. U.S. Envtl. Prot. Agency*, 315 F. Supp. 3d 519, 542 (D.D.C. 2018)).

60. A document is deliberative "if 'it reflects the give-and-take of the consultative process.'" *Louise Trauma Center, LLC v. DOJ*, No. 20-3517, 2022 WL 278771, at *7 (D.D.C. Jan. 30, 2022) (quoting *Am. Oversight v. USPS*, No. 20-cv-2580, 2021 WL 4355401, at *8 (D.D.C. Sept. 23, 2021)).

61. The Medical and Statistical Reviews at issue here are neither "deliberative" nor "predecisional."

62. As noted above, a document loses any predecisional status if it has been "formally or informally adopted as the official agency position." *Pavement Coatings*, 2019 WL 7037527, at *4.

63. Internal agency reviews, such as the Medical Review and Statistical Review here, become part of FDA's final decision on any NDA or sNDA, and thus are officially adopted by the agency.

64. Indeed, once an NDA or sNDA is approved, such reviews are typically posted publicly by the agency as part of a "Drug Approval Package," indicating that they are deemed to be part of the agency's final decision. *See, e.g.*, FDA, *Drug Approval Package: BEOVU (brolucizumab-dbll)*, perma.cc/P85Q-PV3W (Oct. 17, 2019) (containing Medical Review and Statistical Review(s) for approved drug).

65. Moreover, when FDA's decision *not* to approve an NDA/sNDA is challenged in court, Medical Reviews, Statistical Reviews, and other internal reviews are produced as part of the administrative record. *See, e.g.*, Joint Appendix at 26, *Pharm. Mfg. Research Servs., Inc. v. U.S. FDA*, No. 18-1335 (D.C. Cir. Aug. 30, 2019), ECF No. 1804497 (administrative record for denial of NDA included Clinical Review, Cross-Discipline Deputy Director Review, and Summary Division Director Review). FDA must produce the Reviews to defend a decision to deny approval of an NDA or sNDA, as these Reviews are the essential record necessary for the decision itself. This fact indicates that that the Reviews are part of the decision itself—rather than mere "predecisional" precursors to a separate, final decision. In fact, the Reviews are generally *the* critical evidence that forms the basis of FDA's adverse decision with respect to a drug.

66. Because the requested Reviews have been incorporated into the agency's official decision on Vanda's sNDA for Hetlioz®, they are not "predecisional" within the meaning of Exemption 5 and thus are not exempt from FOIA.

67. Here, FDA's Complete Response Letter, issued on August 16, 2019, is plainly a final decision by the agency indicating its definitive view on the issue. FDA concluded, in straightforward terms: "We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form." That is, Vanda filed an

sNDA, and the August 16, 2019 Complete Response Letter was a final, adverse adjudication—and it was one that incorporated factual conclusions rendered by the Reviews.

68. Nor are such reviews "deliberative." To assess whether a document is "deliberative," courts consider "whether disclosure of a document is likely to adversely affect the purposes of the privilege." *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980). Where the contents of a document are "so candid or personal in nature that public disclosure is likely in the future to stifle honest and frank communication within the agency," the document is likely to be privileged. *Id*. "Conversely, '[c]ourts have typically required disclosure of purely factual material, presumably because the prospect of disclosure is less likely to make an advisor omit or fudge raw facts, while it is quite likely to have such an effect on materials reflecting deliberative or policy-making processes.'" *NAACP v. Bureau of the Census*, 401 F. Supp. 3d 608, 612 (D. Md. 2019) (quoting *Quarles v. Dep't of the Navy*, 893 F.2d 390, 392 (D.C. Cir. 1990) (alteration in original).

69. The documents at issue here are not deliberative because they principally contain medical and statistical factual reasoning—that is, they reflect "factual material" that is not within the scope of the privilege. *Quarles*, 893 F.2d at 392. They do not describe matters of opinion, nor do they relate to honest and frank communication within the agency. *See Vaughn v. Rosen*, 523 F.2d 1136, 1143 (D.C. Cir. 1975) ("Unevaluated factual reports or summaries of past administrative determinations are frequently used by decisionmakers in coming to a determination, and yet it is beyond dispute that such documents would not be exempt from disclosure."); *Sterling Drug Inc. v. Harris*, 488 F. Supp. 1019, 1028-29 (S.D,N.Y. 1980) (holding that FDA Reviews "are not a direct part of the deliberative process" because they "are routinely prepared on every NDA

that is submitted," "are investigative scientific reports," and "are factual analyses and descriptions performed by individuals in the course of performing their ongoing investigative responsibilities").

70. Moreover, FDA's assertion of privilege is undercut by its regular practice of making the Reviews available in litigation and on its website. "Exemption 5 requires reference to whether discovery would normally be required during litigation *with the agency*." *FTC v. Grolier Inc.*, 462 U.S. 19, 26 (1983). In litigation against FDA under the Administrative Procedure Act, FDA routinely includes Reviews in the administrative record. *See, e.g.*, Joint Appendix at 26, *Pharm. Mfg. Research Servs., Inc. v. U.S. FDA*, No. 18-1335 (D.C. Cir. Aug. 30, 2019), ECF No. 1804497. That these documents would "routinely" or "normally" be disclosed during agency litigation means that they cannot be withheld under Exception 5.

71. FDA is, in fact, *required* to make the Reviews available to the public in certain circumstances. It must post the "action package" for a drug application on its website "not later than 30 days after the date of approval of such application[]" or "not later than 30 days after the third [FOIA] request for such an action package." 21 U.S.C. § 355(*l*)(2)(A). The action package includes "[d]ocuments generated by the Food and Drug Administration related to review of the application" such as the Reviews at issue here. *Id.* § 355(*l*)(2)(C)(i). FDA guidance accordingly lists "Discipline review memos" as an example of the type of document that must be disclosed. FDA, *SOPP 8401.7: Action Package for Posting*, at 3 (Dec. 11, 2020), *available at* perma.cc/X5JM-Q394.

72. That FDA has interpreted its disclosure obligations under the FDCA to extend to reviews like those requested here is incompatible with its claim of withholding under Exemption 5. The FDCA specifically caveats that its disclosure requirements do "not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter" covered by

a FOIA exemption. 21 U.S.C. § 355(*l*)(2)(E). And FDA's own guidance requires that "[a]ny information exempt from disclosure . . . be redacted before posting." *SOPP 8401.7*, at 4. Yet FDA nevertheless routinely posts Reviews as part of the action packages on its website, indicating that the Agency does not ordinarily consider these documents to be covered by any privilege.

73. Finally, the deliberativeness inquiry focuses at bottom on "whether disclosure of the requested material would tend to discourage candid discussion within an agency." *Pavement Coatings Tech. Council v. U.S. Geological Survey*, 995 F.3d 1014, 1022 (D.C. Cir. 2021) (quoting *Petroleum Info. Corp. v. U.S. Dept. of the Interior*, 976 F.2d 1429, 1434 (1992). It is impossible that disclosure of the Reviews would harm the deliberative process when *the very same documents* are routinely made public once drugs are approved or when agency decisions are challenged in litigation.

74. Even if deliberative process privilege protected these documents, Vanda has "a compelling need for disclosure that overcomes the privilege." *NAACP*, 401 F. Supp. 3d at 617; *accord Judicial Watch, Inc. v. DOJ*, 365 F.3d 1108, 1113 (D.C. Cir. 2004) ("The deliberative process privilege, however, is qualified and can be overcome by a sufficient showing of need"). Vanda has a substantial financial interest in the success of its applications for Hetlioz® to treat Jet Lag Disorder; FDA's refusal to disclose important factual records immediately injures Vanda. And to the extent that any portion of the requested Reviews are deemed privileged, and the privilege is not overcome by Vanda's interests, FDA must produce the non-privileged portions of the documents. *See Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 926 F. Supp. 2d 311, 315 (D.D.C. 2013).

CLAIM

COUNT I

Freedom of Information Act, 5 U.S.C. § 552

75. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-74 as though fully set forth herein.

76. FOIA requires agencies, upon receipt of a request for agency records that reasonably describes the records sought and conforms to applicable procedural rules, to "make the records promptly available." 5 U.S.C. § 552(a)(3)(A).

77. Vanda's FOIA request dated December 2, 2019, reasonably describes the two documents sought and conforms to applicable procedure.

78. The documents Vanda requested are not covered by any FOIA exemption, including Exemption 5.

79. Vanda is thus entitled to an injunction ordering FDA to produce the two requested Reviews, which have been "improperly withheld," immediately. 5 U.S.C. § 552(a)(4)(B).

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor and that the Court:

1. Order that Defendant FDA disclose the requested documents in their entirety and promptly make copies available to Vanda.
2. Award Vanda its costs and reasonable attorney's fees incurred in this action.
3. Award Vanda such other and further relief as the Court may deem just and proper.

Dated: April 6, 2022

Respectfully submitted,

/s/ Paul W. Hughes
Paul W. Hughes (D.C. Bar No. 997235)
Andrew A. Lyons-Berg (D.C. Bar No. 230182)
Charles Seidell* (D.C. Bar No. 1670893)
(**application for admission forthcoming*)
McDermott Will & Emery LLP
500 North Capitol Street, NW
Washington, DC 20001
(202) 756-8000
phughes@mwe.com

Attorneys for Plaintiff