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. 23-2325

COMPLAINT FOR DECLARATORY AND 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. 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.

2. Vanda submitted a FOIA request to FDA in April 2023, seeking reviews prepared by FDA during its consideration of a supplemental New Drug Application (sNDA) for Vanda's drug Hetlioz®.

3. FDA acknowledged Vanda's request by letter dated April 11, 2023. It has not otherwise responded to the request.

4. FDA has failed to make a determination as to Vanda's request within the statutory timeframe. Because of FDA's failure to adhere to the statutory requirements, this Court has jurisdiction to adjudicate the dispute over the requested records now.

5. The Court should declare that FDA's failure to respond, to search for records, and to produce documents in response to Vanda's request violates FOIA and should grant injunctive relief directing FDA to conduct a search and to produce responsive documents to Vanda immediately.

PARTIES

6. Plaintiff Vanda Pharmaceuticals, Inc., is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high-impact unmet medical needs and improve the lives of patients. Vanda is incorporated in Delaware and maintains its principal place of business in Washington, DC.

7. 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

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

9. 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.

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

11. Vanda is not required to further exhaust its administrative remedies because, under FOIA, a requestor of records "shall be deemed to have exhausted his administrative remedies with respect to [a] request if the agency fails to comply with the applicable time limit" for providing a response to a FOIA request. 5 U.S.C. § 552(a)(6)(C)(i). As detailed below, FDA did not provide Vanda with a response to a FOIA request within the time period required by the statute.

BACKGROUND

A. The Driving Study sNDA

12. 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 (NDA) for that drug. 21 U.S.C. § 355(a).

13. Once FDA has approved an NDA for a drug, the manufacturer may lawfully market the drug for the use specified in the NDA. Manufacturers must comply with strict labeling requirements for their drugs and face steep civil and criminal sanctions if they fail to do so. *See generally* 21 U.S.C. § 352. In particular, labeling and marketing materials must not be "false or misleading." *Id.* § 352(a), (q), (bb).

14. Whether a label is false or misleading turns, in part, on differences between the information on the label "and the labeling approved for the drug or device" by FDA. 21 U.S.C. §

352(a)(1). Manufacturers thus often seek FDA approval before including "any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences . . . of the use of a drug." *Id.*

15. If a manufacturer wishes to amend an NDA—including the information on the drug's label—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).

16. Vanda is the owner of NDA 205677 for Hetlioz®, a melatonin receptor agonist. Hetlioz® is approved for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults and Nighttime sleep disturbances in Smith Magenis Syndrome (SMS) in patients 16 years of age or older.

17. Tasimelteon is the active ingredient in Hetlioz®.

18. In 2018, Vanda announced the results of a driving study in which it measured the next-day performance of patients taking tasimelteon. The driving study demonstrated significantly less impairment of driving performance among patients treated with tasimelteon compared to the control.

19. Vanda submitted an sNDA seeking to add information from the driving study to the Hetlioz® label. FDA received the sNDA on November 9, 2018, and designated it No. 205677/S-005.

20. On September 9, 2019, FDA issued a Complete Response Letter (CRL) in response to Vanda's sNDA. A CRL indicates that FDA has determined it will not approve the application in its current state.

B. Vanda's FOIA Request

21. FDA reviewers document their analysis of various components of an application in "discipline reviews."

22. On April 10, 2023,[1] Vanda submitted a FOIA request to FDA seeking any discipline reviews (including the Clinical and Clinical Pharmacology Reviews) prepared by the agency during its evaluation of sNDA 205677/S-005.

23. The Director of FDA's Division of Freedom of Information acknowledged receipt of Vanda's request by letter dated April 11, 2023. Ex. B. She assured Vanda that FDA would "respond as soon as possible." *Id.*

24. Vanda's FOIA request was assigned FOIA Control No. 2023-2856.

LEGAL ARGUMENT

25. 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).

[1] Vanda's FOIA request was inadvertently dated March 31, 2023—the date of an earlier draft. The correct date of submission is April 10.

26. 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)(i).

27. FDA did not satisfy this deadline.

28. This 20-day period can be extended, in "unusual circumstances," by no more than ten additional business days. 5 U.S.C. § 552(a)(6)(B)(i).

29. Even assuming that "unusual circumstances" existed, FDA did not meet its deadline to provide a response. In "unusual circumstances," FDA would have 30 business days from April 11, 2023—*i.e.*, until May 23, 2023—to make a determination as to Vanda's request. FDA did not do so. To date, more than 70 working days have elapsed, and FDA has not provided any records or otherwise issued a determination as to Vanda's request.

30. FOIA allows an agency a *maximum* of thirty working days within which to make a determination on a FOIA request. 5 U.S.C. § 552(a)(6)(A)-(B). The agency must then make responsive, nonexempt records "promptly available" to the requestor. *Id.* § 552(a)(3)(A).

31. It has been nearly four months—more than 70 working days—since FDA acknowledged Vanda's request.

32. "[I]n order to make a 'determination' and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and the reasons for withholding any documents; and (iii) inform the requester that it can appeal

whatever portion of the 'determination' is adverse." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188 (D.C. Cir. 2013).

33. On information and belief, FDA has not satisfied any of these basic requirements. It has not conducted a search for responsive documents. It has not determined—and certainly has not communicated—the scope of documents to be withheld and disclosed. And FDA has not informed Vanda of any determination on the request, including concerning the appealability of any adverse portions of the determination.

34. FDA thus has yet to issue a determination on the request or produce any responsive documents. It has exceeded the maximum statutory thirty-working-day window. 5 U.S.C. § 552(a)(6)(A)-(B).

35. FOIA authorizes a district court to stay proceedings and "allow the agency additional time to complete its review of the records" only if "the Government can show [that] exceptional circumstances exist and that the agency is exercising due diligence in responding to the request." 5 U.S.C. § 552(a)(6)(C)(i). The burden of demonstrating exceptional circumstances is on the agency. *Id.*

36. A stay is not warranted here because FDA cannot show either "exceptional circumstances" or that it is responding to Vanda's request with due diligence.

37. In order to show that exceptional circumstances exist, "[a]n agency must show more than a great number of requests" (*Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 259 n.4 (D.D.C. 2005)); it must also show that "the number of requests received in the

relevant period was truly unforeseen and remarkable," or that it is making progress in reducing its backlog of requests. *Daily Caller News Found. v. FBI*, 387 F. Supp. 3d 112, 116 (D.D.C. 2019).

38. Here, the available data demonstrate that FDA's current load of FOIA requests is neither unforeseen nor remarkable, and that FDA is not making any progress on its backlog.

39. The number of FOIA requests received by FDA each year has remained relatively stable over the last few years. Indeed, the number of requests declined substantially from its peak over the last three years.[2]

Year	**Number of Requests Received by FDA**
FY2022	9,333
FY2021	8,529
FY2020	9,951
FY2019	11,578
FY2018	10,329
FY2017	11,062
FY2016	10,374
FY2015	9,954

40. Given the relative stability of FDA's inflow of requests, FDA cannot credibly claim that its current FOIA workload is unforeseeably or unusually high.

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[2] Data taken from the Department of Health and Human Services' Freedom of Information Annual Reports (https://www.hhs.gov/foia/reports/annual-reports/index.html).

41. The data also indicate that FDA has not been making reasonable progress in reducing its backlog of requests. On the contrary, the data indicate that FDA's backlog has stayed relatively flat—and even grown substantially in the most recent fiscal years with reported data.[3]

Fiscal Year	Number of Backlogged Requests at FY End
FY2022	4,188
FY2021	3,577
FY2020	2,825
FY2019	3,172
FY2018	2,666
FY2017	2,279
FY2016	2,248
FY2015	2,337

42. Because FDA is neither dealing with an unforeseen level of FOIA requests nor making progress on its FOIA backlog, it cannot show the "exceptional circumstances" required to warrant a stay.

43. Even if "exceptional circumstances" existed, a stay would be unwarranted because FDA cannot show that it is responding to Vanda's request with due diligence.

[3] Data taken from the Department of Health and Human Services' Freedom of Information Annual Reports (https://www.hhs.gov/foia/reports/annual-reports/index.html).

44. The documents Vanda seeks are not subject to withholding under a FOIA exemption. In recent litigation concerning an analogous request, this Court confirmed that discipline reviews must be produced in response to requests from drug sponsors. See *Vanda Pharmaceuticals v. FDA*, No. 22-cv-938, 2023 WL 2645714 (D.D.C. Mar. 27, 2023). The request at issue in that case sought discipline reviews connected to a different sNDA for Hetlioz®. FDA has since produced reviews to Vanda, as required by the district court.

CLAIMS

COUNT I

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Conduct an Adequate Search

45. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-44 as though fully set forth herein.

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

47. Vanda's FOIA request submitted April 10, 2023, reasonably describes documents sought and conforms to applicable procedure. FOIA therefore requires FDA to make a determination on the request and to produce documents without delay.

48. FDA's failure to conduct a reasonable search for records responsive to Vanda's FOIA request violates 5 U.S.C. § 552(a)(3)(C).

COUNT II

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Respond within Time Required

49. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-48 as though fully set forth herein.

50. FOIA requires agencies, upon receipt of a request for agency records that reasonably describes the records sought and conforms to applicable procedural rules, to "determine . . . whether to comply with such request" and "immediately notify the person making such request." 5 U.S.C. § 552(a)(6)(A)(i). FDA must make this determination "within 20 days (excepting Saturdays, Sundays, and legal public holidays)" and permits a ten business-day extension in "exceptional circumstances" for a maximum of 30 business days. 5 U.S.C. § 552(a)(6)(A)(i), (B)(i).

51. Vanda's FOIA request submitted April 10, 2023, reasonably describes documents sought and conforms to applicable procedure. FOIA therefore requires FDA to make a determination on the request and to produce responsive documents without delay.

52. To date, FDA has not responded to Vanda's request. FDA's 30-business-day deadline has passed. FDA's failure to respond to Vanda's request thus violates FOIA.

COUNT III

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Provide Responsive Records

53. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-52 as though fully set forth herein.

54. 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).

55. Vanda's FOIA request submitted April 10, 2023, reasonably describe documents sought and conforms to applicable procedure. FOIA therefore requires FDA to produce responsive documents without delay.

56. The documents described in the request are not subject to withholding under any FOIA exemption.

57. FDA's failure to provide the responsive, nonexempt records thus violates FOIA.

PRAYER FOR RELIEF

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

1. Declare that FDA's failure to respond, search, or produce responsive documents for more than thirty working days after the receipt of Vanda's request violates FOIA.
2. Order that Defendant FDA expeditiously conduct an adequate search for all records responsive to Vanda's FOIA request.
3. Order that Defendant FDA process and disclose the requested documents in their entirety and promptly make copies available to Vanda.
4. Award Vanda its costs and reasonable attorney's fees incurred in this action.
5. Award Vanda such other and further relief as the Court may deem just and proper.

Dated: August 11, 2023

Respectfully submitted,

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