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. 24-356

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 October 2023, seeking internal FDA documents relating to Vanda's drug Fanapt® (iloperidone).

3. FDA acknowledged Vanda's request on October 10, 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, or 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 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 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. Vanda's interactions with FDA concerning iloperidone

12. Fanapt® (iloperidone) is an atypical antipsychotic that acts as a dopamine and serotonin receptor antagonist. Fanapt® blocks both (i) dopamine 2 receptors, which reduces the positive symptoms of psychosis and stabilizes affective symptoms, and (ii) serotonin 2A receptors, which causes enhanced dopamine release in certain brain regions thus reducing motor side effects and, potentially, improves cognitive and affective symptoms.

13. Vanda is the owner of NDA No. 022192, which permits it to market Fanapt® for the treatment of schizophrenia in adults. Iloperidone, the active ingredient in Fanapt®, is an atypical antipsychotic.

14. Fanapt® was originally approved by FDA on May 6, 2009.

15. Vanda has devoted significant resources to researching the efficacy of using iloperidone to treat other psychological disorders.

16. As a result of that research, Vanda has submitted a supplemental new drug application to FDA, seeking to add new indications for iloperidone.

17. In June 2023, for example, Vanda filed a Supplemental New Drug Application (sNDA) with FDA, seeking approval to market Fanapt® for the treatment of bipolar mania. Bipolar mania is a phase of bipolar disorder characterized by an abnormally heightened mood state and accompanied by hyperactivity and reduced need for sleep.

B. Vanda's FOIA Request

18. On October 6, 2023, Vanda submitted a FOIA request to FDA seeking "any internal communications . . . relating to any aspect of Vanda's development programs, applications, approvals, or otherwise concerning the drug Fanapt®," including any supplemental New Drug Applications deriving from that NDA. *See* Ex. A.

19. The Director of FDA's Division of Freedom of Information acknowledged receipt of the internal communications request by letter dated October 10, 2023. Ex. B. She assured Vanda that FDA would "respond as soon as possible." *Id.*

20. Vanda's request was assigned FOIA Control No. 2023-8869.

LEGAL ARGUMENT

21. 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).

22. 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).

23. FDA did not satisfy this deadline.

24. 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).

25. 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 October 10, 2023, to make a determination as to Vanda's request. FDA did not do so. To date, over three months have elapsed, and FDA has not provided any records or otherwise issued a determination as to Vanda's request.

26. 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).

27. It has been over three months since FDA acknowledged Vanda's request.

28. "[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).

29. 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.

30. 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).

31. 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.*

32. 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.

33. 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)).

34. 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.

35. 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.[1]

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

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

[1] 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).

37. 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.[2]

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

38. 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.

39. 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.

[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).

CLAIMS

COUNT I

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

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

41. 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).

42. Vanda's FOIA request dated October 6, 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.

43. 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

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

45. 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 FOIA permits a ten business-day extension in "exceptional circumstances" for a maximum of 30 business days. *Id.* § 552(a)(6)(A)(i), (B)(i).

46. Vanda's FOIA request dated October 6, 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.

47. 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

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

49. 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).

50. Vanda's FOIA request dated October 6, 2023, reasonably describes documents sought and conforms to applicable procedure. FOIA therefore requires FDA to produce responsive documents without delay.

51. 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, conduct a search, or produce responsive documents for more than three months 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: February 6, 2024

Respectfully submitted,

/s/ *Paul W. Hughes*

Paul W. Hughes (D.C. Bar No. 997235)
Sarah P. Hogarth (D.C. Bar No. 1033884)
Charles Seidell (D.C. Bar. No. 1670893)
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000
phughes@mwe.com

Attorneys for Plaintiff