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. 23-2327

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 three FOIA requests to FDA in March 2023, seeking bioequivalence study and dissolution study data, reports, and summaries submitted by applicants seeking to market generic copies of Vanda's drug Hetlioz® (tasimelteon).

3. FDA acknowledged Vanda's requests by letters dated March 15, 2023. It has not otherwise responded to the requests.

4. FDA has failed to make a determination as to any of Vanda's requests 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 requests 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 requests within the time period required by the statute.

BACKGROUND

A. Hetlioz® and tasimelteon NDAs

12. 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.

13. 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.

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

15. Vanda has devoted significant resources to researching the efficacy of using tasimelteon to treat other sleep-related disorders.

16. Congress passed the Hatch-Waxman Amendments "to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbot Labs. V. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting); *accord Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) ("The Hatch–Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by similar regulatory requirements.").

17. The Amendments created a new mechanism—the Abbreviated New Drug Application (ANDA)—by which generic manufacturers could obtain accelerated, less burdensome approval by piggybacking off the pioneer drug's NDA. *See* 21 U.S.C. § 355(j).

18. The ANDA provision "allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). Instead, generic manufacturers need only submit "information to show that the new drug is bioequivalent to the listed drug" and that the labeling, route of administration, dosage form, and strength is the same. 21 U.S.C. § 355(j)(iii)-(v).

19. To date, FDA has reviewed and approved three ANDAs seeking permission to market generic versions of Hetlioz®.

20. On information and belief, Teva Pharmaceuticals submitted ANDA No. 211601 to FDA on or about January of 2018. FDA received the ANDA on January 31, 2018.

21. FDA issued a tentative approval for Teva's ANDA on September 27, 2021. FDA issued a final approval for Teva's ANDA on December 12, 2022.

22. On information and belief, Apotex Corp. submitted ANDA No. 211607 to FDA on or about January of 2018. FDA received Apotex's ANDA on January 31, 2018.

23. FDA issued a tentative approval for Apotex's ANDA on February 3, 2020. FDA issued a final approval for Apotex's ANDA on December 20, 2022.

24. On information and belief, MSN Pharmaceuticals Inc. submitted ANDA No. 211654 to FDA on or about January of 2018. FDA received the ANDA on January 31, 2018.

25. FDA issued a tentative approval for MSN's ANDA on May 28, 2020. FDA issued a final approval for MSN's ANDA on January 12, 2023.

B. Vanda's FOIA Requests

26. On March 14, 2023, Vanda submitted a FOIA request to FDA seeking, among other records, "[a]ny bioequivalence study or dissolution study data, complete study reports, or summary study reports submitted during FDA's consideration of" Teva's ANDA. *See* Ex. A.

27. The Director of FDA's Division of Freedom of Information acknowledged receipt of Vanda's request by letter dated March 15, 2023. Ex. B. She assured Vanda that FDA would "respond as soon as possible." *Id.*

28. Vanda's FOIA request for Teva's bioequivalence and dissolution submission was assigned FOIA Control No. 2023-2018. Ex. B.

29. On March 14, 2023, Vanda submitted a FOIA request to FDA seeking, among other records, "[a]ny bioequivalence study or dissolution study data, complete study reports, or summary study reports submitted during FDA's consideration of" Apotex's ANDA. *See* Ex. C.

30. The Director of FDA's Division of Freedom of Information acknowledged receipt of Vanda's request by letter dated March 15, 2023. Ex. D. She assured Vanda that FDA would "respond as soon as possible." *Id.*

31. Vanda's FOIA request for Apotex's bioequivalence and dissolution submission was assigned FOIA Control No. 2023-2019. Ex. D.

32. On March 14, 2023, Vanda submitted a FOIA request to FDA seeking, among other records, "[a]ny bioequivalence study or dissolution study data, complete study reports, or summary study reports submitted during FDA's consideration of" MSN's ANDA. *See* Ex. E.

33. The Director of FDA's Division of Freedom of Information acknowledged receipt of Vanda's request by letter dated March 15, 2023. Ex. F. She assured Vanda that FDA would "respond as soon as possible." *Id.*

34. Vanda's FOIA request for MSN's bioequivalence and dissolution submission was assigned FOIA Control No. 2023-2016. Ex. F.

LEGAL ARGUMENT

35. FDA requires ANDA applicants "to submit data on all [bioequivalence] studies, including studies that do not meet passing bioequivalence criteria." *See* 74 Fed. Reg. 2849 (Jan. 16, 2009); 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.").

36. 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."). 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.*

37. The documents Vanda requested thus necessarily exist, are identifiable, and given FDA's guarantee of public availability are not subject to withholding in full.

38. 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).

39. 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).

40. FDA did not satisfy this deadline.

41. 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).

42. 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 March 14, 2023—*i.e.*, until April 27, 2023—to make a determination as to Vanda's requests. FDA did not do so. To date, nearly five months have elapsed, and FDA has not provided any records or otherwise issued a determination as to Vanda's requests.

43. 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).

44. It has been over thirty working days since FDA acknowledged Vanda's requests.

45. "[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).

46. 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 requests, including concerning the appealability of any adverse portions of the determination.

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

48. 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.*

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

50. 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).

51. 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.

52. 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 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

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

54. 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]

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[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).

[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).

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

55. 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.

56. 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.

CLAIMS

COUNT I

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Conduct an Adequate Search, Request No. 2023-2018

57. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-56 as though fully set forth herein.

58. 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).

59. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2018, 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.

60. 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, Request No. 2023-2018

61. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-60 as though fully set forth herein.

62. 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).

63. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2018, 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.

64. 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, Request No. 2023-2018

65. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-64 as though fully set forth herein.

66. 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).

67. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2018, reasonably describes documents sought and conforms to applicable procedure. FOIA therefore requires FDA to produce responsive documents without delay.

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

COUNT IV

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Conduct an Adequate Search, Request No. 2023-2019

69. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-68 as though fully set forth herein.

70. 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).

71. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2019, 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.

72. 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 V

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Respond within Time Required, Request No. 2023-2019

73. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-72 as though fully set forth herein.

74. 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).

75. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2019, 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.

76. 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 VI

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Provide Responsive Records, Request No. 2023-2019

77. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-64 as though fully set forth herein.

78. 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).

79. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2019, reasonably describes documents sought and conforms to applicable procedure. FOIA therefore requires FDA to produce responsive documents without delay.

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

COUNT VII

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Conduct an Adequate Search, Request No. 2023-2016

81. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-80 as though fully set forth herein.

82. 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).

83. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2016, 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.

84. 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 VIII

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Respond within Time Required, Request No. 2023-2016

85. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-84 as though fully set forth herein.

86. 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).

87. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2016, 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.

88. 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 IX

Freedom of Information Act, 5 U.S.C. § 552 — Failure to Provide Responsive Records, Request No. 2023-2016

89. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-88 as though fully set forth herein.

90. 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).

91. Vanda's FOIA request dated March 14, 2023, which FDA assigned control no. 2023-2016, reasonably describes documents sought and conforms to applicable procedure. FOIA therefore requires FDA to produce responsive documents without delay.

92. 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 requests violates FOIA.
2. Order that Defendant FDA expeditiously conduct an adequate search for all records responsive to Vanda's FOIA requests.
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,

/s/ Paul W. Hughes
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