In the United States District Court

FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY, 518 C Street, NE Suite 200 Washington, DC 20002 *Plaintiff,* v. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Ave **Silver Spring, Maryland 20993-0002** *Defendant.*	)	Case No. 22-669 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. NATURE OF ACTION

1. The Center for Food Safety (CFS)—a nonprofit public interest and environmental advocacy organization working to protect public health and the environment—brings this civil action under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, challenging the United States Food and Drug Administration's (FDA) unlawful withholding of records that pertain to FDA's assessments of AquaBounty's AquAdvantage salmon drug application.

2. CFS filed a FOIA request with FDA to obtain information relating to FDA's assessments of AquaBounty's AquAdvantage salmon drug applications under three federal statutes.[1] Specifically, CFS hoped to gain insight into FDA's updated assessments as required by the Northern District of California's order,[2] and related to the new AquAdvantage salmon production facility in Ohio. The goal of the request was to open the operations and activities of government to public scrutiny and contribute significantly to the public's understanding of the agency's actions.

3. FDA is violating FOIA by failing to produce records in response to CFS's FOIA request, failing to conduct an adequate search for responsive records, and by failing to provide both an initial determination as to the scope of the records to be produced or withheld, and an estimated date by which the agency's search will be complete.

4. FDA's unlawful withholding of public records undermines FOIA's basic purpose of government transparency. Because prompt access to these records is necessary to effectuate FOIA's

[1] The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, the National Environmental Policy Act, 42 U.S.C. § 4321 *et seq.*, and the Endangered Species Act, 16 U.S.C. § 1531 *et seq.*
[2] *Inst. for Fisheries Resources v. U.S. Food and Drug Admin.*, 499 F. Supp. 657 (N.D. Cal. 2020).

purpose, CFS seeks declaratory relief establishing that FDA is in violation of FOIA, and injunctive relief directing FDA to provide responsive records without any further delay.

II. JURISDICTION AND VENUE

5. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552(a)(4)(B). This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331.

6. Venue properly vests in this Court pursuant to 5 U.S.C. § 552(a)(4)(B), which expressly provides a venue for FOIA cases in the District Court of the District of Columbia.

7. Declaratory relief is appropriate under 28 U.S.C. § 2201.

8. Injunctive relief is appropriate under 28 U.S.C. § 2202 and 5 U.S.C. § 552(a)(4)(B).

III. PARTIES

9. Plaintiff CFS is a national 501(c)(3) nonprofit public interest and environmental advocacy organization that empowers people, supports farmers, and protects the environment from the harms of industrial food production. CFS is a member-oriented non-profit organization with over one million members that works to address the impacts of the food system on public health, animal welfare, and the environment. Through nearly two decades of involvement in public interest and environmental litigation and policymaking as it relates to food, CFS has demonstrated its ability to take technical information provided by government agencies and distill it into a format that is accessible to the public. CFS employs science and policy experts who have analyzed FOIA, other federal environmental laws, and other environmental and scientific reports for their entire careers. CFS puts out reports on a range of food and agricultural topics, including

aquaculture, genetically engineered foods, pesticides, and other topics that tend to be difficult for the layperson to understand without professional assistance. CFS has been engaged in ongoing efforts to educate our members and the public about the harms to public health and the environment from genetically engineered (GE) foods, including the novel GE salmon. CFS and its members understand that there could be serious environmental consequences of approving GE salmon and wish to know more information about the extent of plans to grow and commercialize the salmon in the U.S. CFS and its members are harmed by FDA's violations of FOIA, as such violations preclude CFS from gaining a full understanding of the decision-making process regarding the underlying agency actions and prevent CFS from disseminating information to the public concerning FDA's oversight and environmental review of AquaBounty's GE salmon.

10. Defendant FDA is an agency within the United States Government. FDA is in possession and control of the records that CFS seeks and is an agency within the meaning of 5 U.S.C. § 552(f)(1). FDA is therefore subject to FOIA.

IV. LEGAL BACKGROUND

11. The basic purpose of FOIA is to promote government transparency and public oversight of agency action. The statute effectuates this objective by establishing the public's right to access all federal agency records unless such records may be withheld pursuant to one of nine, narrowly construed exemptions. 5 U.S.C. § 552(b)(1)-(9).

12. FOIA imposes stringent deadlines on federal agencies for making initial determinations in response to FOIA requests. Within twenty working days of receiving a FOIA request, an agency must determine whether it will release the requested records, and must notify

the requester of its determination, the reasons for its decision, and the requester's right to appeal an adverse decision to the head of the agency. *Id.* § 552(a)(6)(A).

13. Congress has specified certain limited instances in which federal agencies may extend this twenty-working-day deadline. First, an agency may toll the deadline to seek additional information or clarification from a requester, but that tolling period ends when the agency receives such information or clarification. *Id.* § 552(a)(6)(A)(ii). Second, in "unusual circumstances" an agency may extend the deadline no more than ten additional working days by providing written notice to the requester that sets forth the circumstances justifying the extension. *Id.* § 552(a)(6)(B)(i).

14. FOIA requires that a determination under 5 U.S.C. § 552(a)(6)(A) "must be more than just an initial statement that the agency will generally comply with a FOIA request and will produce non-exempt documents and claim exemptions in the future." *Citizens for Responsibility and Ethics in Wash. v. Fed. Election Comm'n*, 711 F.3d 180, 188 (D.C. Cir. 2013).

15. For a determination to 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." *Id.* at 188.

16. If the agency fails to respond within the applicable time limit, the requester "shall be deemed to have exhausted his administrative remedies." 5 U.S.C. § 552(a)(6)(C)(i).

17. Such constructive exhaustion[3] "allows immediate recourse to the courts to compel the agency's response to a FOIA request." *Oglesby v. U.S. Dep't of Army*, 920 F.2d 57, 62, 64 (D.C. Cir. 1990).

18. The court "then has the authority to oversee and supervise the agency's progress in responding to the request." *Seavey v. DOJ*, Case No. 15–1303, 2017 WL 3112816, at *2 (D.D.C. July 20, 2017) (citing *Citizens for Responsibility and Ethics in Wash.*, 711 F.3d at 189); *see also Clemente v. FBI*, 71 F. Supp. 3d 262, 269 (D.D.C. 2014) (a court "may use its equitable powers to require the agency to process documents according to a court-imposed timeline.").

19. FOIA requires each agency to search for records in a manner that is reasonably calculated to locate all records that are responsive to the FOIA request. 5 U.S.C. § 552(a)(3)(C)-(D).

20. Regarding production of responsive records, "FOIA requires that the agency make the records 'promptly available,' which depending on the circumstances typically would mean within days or a few weeks of a 'determination,' not months or years." *Citizens for Responsibility and Ethics in Wash.*, 711 F.3d at 188 (citing 5 U.S.C. § 552(a)(3)(A), (a)(6)(C)).

21. In certain limited instances, an agency may withhold records or portions of records pursuant to nine specific exemptions. 5 U.S.C. § 552(b). These exemptions must be "construed narrowly in keeping with FOIA's presumption in favor of disclosure." *Pub. Citizen, Inc. v. Office of Mgmt. & Budget*, 598 F.3d 865, 869 (D.C. Cir. 2010).

[3] "Constructive exhaustion is determined by the actions (or lack thereof) an agency has taken by the time a suit is filed in the district court." *Wisdom v. U.S. Tr. Program*, 232 F. Supp. 3d 97, 113 (D.D.C. 2017) (citing *Oglesby*, 920 F.2d at 64).

22. FOIA places the burden on the agency to prove that it may withhold responsive records or portions of records from a requester. 5 U.S.C. § 552(a)(4)(B).

23. FOIA provides this Court jurisdiction "to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." *Id.* § 552(a)(4)(B).

24. In addition, FOIA provides a waiver for fees associated with the procurement of documents subject to FOIA requests. Such fee waivers are granted "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." *Id.* § 552(a)(4)(A)(iii).

25. Finally, FOIA requires that the agency provide "information about the status of a request . . . including . . . an estimated date on which the agency will complete action on the request." 5 U.S.C. § 552(a)(7)(B)(ii). Failure to respond to multiple requests for an estimated date of completion is actionable. *Muttitt v. U.S. Central Command*, 813 F. Supp. 2d 221, 230-31 (D.D.C. 2011).

V. FACTUAL BACKGROUND

26. CFS, through its GE Food program, works to protect public health and the environment from the impacts of GE salmon, the first GE animal approved for human consumption. CFS has a long history of promoting greater oversight concerning the environmental and agricultural impacts of GE crops and animals.

27. On October 22, 2021, CFS submitted a FOIA request to FDA, seeking "[a]ll documents from November 5, 2020 to present related to FDA's FDCA, NEPA, and ESA

assessments of AquaBounty's AquAdvantage salmon drug application, pursuant to the Northern District of California's order. Specifically including documents related to new drug production facility in Ohio." This is an extremely narrow request, in terms of the date range (less than one year) and content.

28. CFS explained that release of the requested records was in the public's best interest because disclosure would significantly contribute to public understanding of the operations or activities of government, and because obtaining the information was of no commercial interest to CFS.

29. On October 22, 2021, FDA sent CFS an acknowledgement letter with a tracking number for the request (2021-7192). Exhibit A.

30. An initial determination on the October 2021 FOIA request was due by November 19, 2021, twenty working days after the date CFS submitted the request.

31. On January 19, 2022, CFS emailed FDA requesting an initial determination and an estimated date of completion for the October 22, 2021 FOIA request. Exhibit A.

32. On January 28, 2022, FDA emailed CFS acknowledging the request and explaining that the request had not yet been processed, but not providing an initial determination under 5 U.S.C. § 552(a)(6)(A) or an estimated date of completion. Instead, FDA noted that estimated wait time for processing the request is 18-24 months.

33. On February 9, 2022, CFS responded, noting that FDA's response was not an initial determination or estimated date of completion, as required by FOIA.

34. Over four months have passed since FDA logged in the October 22, 2021 FOIA Request, yet FDA has not provided an initial determination in response to the October 22, 2021 FOIA Request, supplied an estimated date of completion, or produced any responsive records.

35. As of the date of this complaint, CFS has received no further communications from FDA.

36. None of FOIA's nine exemptions to the statute's disclosure mandate apply to the records that responsive to the October 22 FOIA Request.

37. CFS has been required to expend resources to prosecute this action.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION
Defendant Failed to Comply with FOIA's Mandatory Determination Deadline

38. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

39. FDA violated FOIA by failing to make a determination on CFS's October 22 FOIA Request. 5 U.S.C. § 552(a)(6).

40. CFS has a statutory right to receive a determination within the congressionally-mandated deadline of twenty working days. *Id.*

41. To date—over four months since CFS filed the October 22 FOIA Request—FDA has not provided a determination, notwithstanding the requirement of 5 U.S.C. § 552(a)(6)(A) of an agency response within twenty working days detailing the scope of the records the agency intends to produce and withhold, the reasons for making that determination, and an explanation of the process by which a requester can administratively appeal that determination.

42. FDA's failure to make an initial determination about the October 22 FOIA Request, thus unlawfully delaying its response beyond the deadline that FOIA mandates, has prejudiced CFS's ability to timely obtain public records. *Id.* § 552(a)(6)(A)(i).

43. As such, CFS has exhausted the applicable administrative remedies with respect to the October 22 FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(C)(i).

44. Due to the nature of CFS's organizational activities, it will undoubtedly continue to employ FOIA's provisions in record requests to FDA in the foreseeable future.

45. CFS's organizational activities will be adversely affected if FDA continues to violate FOIA by failing to disclose responsive records as it has in this case.

46. Unless enjoined and made subject to a declaration of CFS's legal rights by this Court, FDA will continue to violate CFS's rights to receive public records under FOIA.

SECOND CAUSE OF ACTION
Defendant Failed to Conduct an Adequate Search for Responsive Records

47. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

48. FDA violated FOIA by failing to conduct an adequate search for responsive records pursuant to 5 U.S.C. § 552(a)(3)(C)-(D).

49. CFS has a statutory right to have FDA process its October 22 FOIA Request in a manner that complies with FOIA. *Id.*

50. FDA violated CFS's right when it unlawfully failed to undertake a search that is reasonably calculated to locate all records that are responsive to the October 22 FOIA Request, thus prejudicing CFS's ability to timely obtain public records.

51. CFS has exhausted the applicable administrative remedies with respect to the October 22 FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(C)(i).

52. Due to the nature of CFS's organizational activities, it will undoubtedly continue to employ FOIA's provisions in record requests to FDA in the foreseeable future.

53. CFS's organizational activities will be adversely affected if FDA continues to violate FOIA by failing to disclose responsive records as it has in this case.

54. Unless enjoined and made subject to a declaration of CFS's legal rights by this Court, FDA will continue to violate CFS's rights to receive public records under FOIA.

THIRD CAUSE OF ACTION
Defendant Unlawfully Withheld All Responsive Records

55. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

56. FDA violated FOIA by failing to promptly disclose records that are responsive to CFS's October 22FOIA Request. 5 U.S.C. § 552(a)(4)(B).

57. CFS has a statutory right to the records it seeks, and there are no applicable exemptions under FOIA that provide a legal basis for FDA to withhold these records from CFS. *See id.* § 552(b)(1)-(9).

58. To date, FDA has not provided any records requested by CFS in the October 22 FOIA Request, notwithstanding the requirement of 5 U.S.C. § 552(a)(3)(A) and 5 U.S.C. § 552(a)(6)(C) to make agency records "promptly available."

59. As such, FDA is wrongfully withholding disclosure of information sought by CFS, information to which it is entitled and for which no valid disclosure exemption has been claimed. FDA's unlawful withholding prejudices CFS's ability to timely obtain public records.

60. CFS has exhausted the applicable administrative remedies with respect to the October 22 FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(C)(i).

61. Due to the nature of CFS's organizational activities, it will undoubtedly continue to employ FOIA's provisions in record requests to FDA in the foreseeable future.

62. CFS's organizational activities will be adversely affected if FDA continues to violate FOIA by failing to disclose responsive records as it has in this case.

63. Unless enjoined and made subject to a declaration of CFS's legal rights by this Court, FDA will continue to violate CFS's rights to receive public records under FOIA.

FOURTH CAUSE OF ACTION
Defendant Failed to Provide Reasonably Segregable Portions of Any Lawfully Exempt Records

64. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

65. FDA violated FOIA by failing to take reasonable steps to segregate and release nonexempt portions of lawfully exempt records in response to the October 22 FOIA Request. 5 U.S.C. § 552(a)(8)(A)(ii)(II).

66. CFS has a statutory right to any reasonably segregable portion of a record that contains information that is subject to any of FOIA's exemptions. *Id.*

67. To date, FDA has failed to disclose any records to CFS, including nonexempt information that could be reasonably segregated and released in response to the October 22 FOIA Request, thus prejudicing CFS's ability to timely obtain public records.

68. CFS has exhausted the applicable administrative remedies with respect to the October 22 FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(C)(i).

69. Due to the nature of CFS's organizational activities, it will undoubtedly continue to employ FOIA's provisions in record requests to FDA in the foreseeable future.

70. CFS's organizational activities will be adversely affected if FDA continues to violate FOIA by failing to disclose responsive records as it has in this case.

71. Unless enjoined and made subject to a declaration of CFS's legal rights by this Court, FDA will continue to violate CFS's rights to receive public records under FOIA.

FIFTH CAUSE OF ACTION
Defendant Failed to Provide an Estimated Date of Completion as Required by FOIA

72. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

73. FDA violated FOIA by failing to provide CFS with an estimated date of completion as required by 5 U.S.C. § 552(a)(7)(A)-(B).

74. CFS has a statutory right to have FDA process its October 22 FOIA Request in a manner which complies with FOIA. FDA has violated Plaintiff's rights in this regard by its failure to provide—by any means—an estimated completion date for its response to the October 22 FOIA Request as required by FOIA. 5 U.S.C. § 552(a)(7)(A)-(B).

75. FDA's failure to inform CFS of an estimated completion date for the October 22 FOIA Request has prejudiced CFS's ability to timely obtain public records.

76. CFS has exhausted the applicable administrative remedies with respect to the October 22 FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(C)(i).

77. Due to the nature of CFS's organizational activities, it will undoubtedly continue to employ FOIA's provisions in record requests to FDA in the foreseeable future.

78. CFS's organizational activities will be adversely affected if FDA continues to violate FOIA by failing to disclose responsive records as it has in this case.

79. Unless enjoined and made subject to a declaration of CFS's legal rights by this Court, FDA will continue to violate CFS's rights to receive public records under FOIA.

REQUESTS FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

1. Order Defendant to provide a lawful initial determination on Plaintiff's FOIA request as required by FOIA by a date certain;

2. Order Defendant to conduct searches that are reasonably calculated to locate all records responsive to Plaintiff's October 22 FOIA Request with the cut-off date for searches being the date the searches are conducted, and to provide to Plaintiff, by a date certain, with all responsive records and reasonably segregable portions of lawfully exempt records sought in this action.

3. Declare that Defendant unlawfully failed to make and communicate an initial determination on Plaintiff's October 22 FOIA Request as required by 5 U.S.C. § 552(a)(6)(A)(i).

4. Declare that Defendant unlawfully failed to undertake a search and disclosure of all records responsive to Plaintiff's October 22 FOIA Request as required by 5 U.S.C. § 552(a)(6)(A)(i).

5. Declare that Defendant unlawfully failed to provide Plaintiff with reasonably segregable portions of records which may be lawfully subject to a FOIA exemption as required by 5 U.S.C. § 552(a)(7)(b).

6. Declare that Defendant unlawfully failed to provide Plaintiff with an estimated date of completion as to the search and production of Plaintiff's October 22 FOIA Request as required by 5 U.S.C. § 552(a)(7)(B)(ii).

7. Provide for expeditious proceedings in this action.

8. Award Plaintiff its costs and reasonable attorney fees pursuant to 5 U.S.C. § 552(a)(4)(E) or 28 U.S.C. § 2412.

9. Grant such other relief as the Court may deem appropriate.

Dated this 10th day of March, 2022.

Respectfully submitted,

CENTER FOR FOOD SAFETY,

/s/ Amy van Saun
Amy van Saun (OR0020)
Center for Food Safety
2009 NE Alberta Street, Suite 207
Portland, Oregon 97211
(585) 747-0151
Email: avansaun@centerforfoodsafety.org

Counsel for Plaintiff