

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

INFORMED CONSENT ACTION NETWORK,
2025 Guadalupe Street, Suite 260
Austin, Texas 78705

Plaintiff,

-against-

FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Defendant.

Civil Action No. 1:23-cv-219

COMPLAINT

Plaintiff Informed Consent Action Network (“**ICAN**” or “**Plaintiff**”) brings this action against defendant Food and Drug Administration (“**FDA**” or “**Defendant**”) to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 (“**FOIA**”). As grounds therefor, Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.
2. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

PARTIES

3. Plaintiff ICAN is a not-for-profit organization with an office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705.

4. Defendant FDA is an agency within the Executive Branch of the United States Government, organized within the U.S. Department of Health and Human Services. FDA is an agency within the meaning of 5 U.S.C. § 552(f) and has possession, custody, and control of records to which Plaintiff seeks access.

5. On June 30, 2022, Plaintiff sent a FOIA request to FDA seeking copies of the following records:

All records concerning “Empirical Bayesian data mining” and “Empirical Bayesian Geometric Means” pursuant to Section 2.3 (2.3.2) of the VAERS Standard Operating Procedures for COVID-19.¹ This should include, but not be limited to, any communications between FDA and CDC “shar[ing] and discuss[ing] results of data mining analyses and signals.” (See Section 2.3.2)

(**Exhibit 101** at 9.) (Footnote included.)

6. On August 26, 2022, FDA issued a final response stating it was denying the entire request (FOIA #2022-4855) pursuant to 5 U.S.C. § 552(b)(5) (“Exemption 5”). (See **Exhibit 101** at 17.)

7. On October 31, 2022, Plaintiff appealed FDA’s final response challenging the adequacy of its search and its improper use of FOIA Exemption 5. (**Exhibit 101** at 1-7.)

8. FDA acknowledged receipt of Plaintiff’s appeal on November 1, 2022 and assigned it appeal file 22-000131AA. (**Exhibit 102.**) In FDA’s acknowledgement letter, it stated in part, the following:

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 CFR 5.24(f) of the HHS FOIA regulations, your appeal falls under “unusual circumstances” in that our office will need to consult with another office that has substantial interest in the determination of the appeal. The actual

¹ See <https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf>.

processing time will depend on the complexity of the issues presented in the appeal.

(Exhibit 102.)

9. In violation of the time limits prescribed by 5 U.S.C. § 552(a)(6)(A)(ii) and 5 U.S.C. § 552(a)(6)(B)(i), as of the date of this Complaint, FDA has failed to make a determination with respect to Plaintiff's appeal.

COUNT I
FAILURE TO MAKE DETERMINATION BY REQUIRED DEADLINE
(VIOLATION OF FOIA, 5 U.S.C. § 552)

10. Plaintiff realleges paragraphs 1 through 9 as if fully stated herein.

11. Defendant was required to make a determination on Plaintiff's appeal no later than December 14, 2022.

12. Defendant failed to make a determination on Plaintiff's appeal within the time limits set forth by FOIA; therefore, Plaintiff is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(A)(ii); 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(C)(i).

13. Defendant is in violation of FOIA.

COUNT II
FAILURE TO ESTABLISH ADEQUACY OF SEARCH
(VIOLATION OF FOIA, 5 U.S.C. § 552)

14. Plaintiff realleges paragraphs 1 through 13 as if fully stated herein.

15. For appeal file 22-000131AA, Defendant has failed to establish that it adequately searched for responsive records despite Plaintiff's challenge to same in Plaintiff's appeal.

16. Defendant is in violation of FOIA.

COUNT III
IMPROPER WITHOLDING OF RECORDS
(VIOLATION OF FOIA, 5 U.S.C. § 552)

17. Plaintiff realleges paragraphs 1 through 16 as if fully stated herein.

18. For appeal file 22-000131AA, Defendant has failed to establish the validity of its claimed exemption despite Plaintiff challenging the same in Plaintiff's appeal.

19. Defendant is in violation of FOIA.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

a. Declare that Defendant's continued delay in processing Plaintiff's FOIA appeal is unlawful under FOIA;

b. Declare that Defendant has failed to conduct an adequate search for responsive records as required by FOIA;

c. Declare that Defendant improperly withheld responsive records under Exemption 5;

d. Order Defendant to conduct searches for any and all records responsive to Plaintiff's FOIA request and demonstrate that it employed search methods reasonably likely to lead to the discovery of records responsive to a broad interpretation of Plaintiff's FOIA request;

e. Order Defendant to produce, by a date certain, any and all non-exempt records responsive to Plaintiff's FOIA request and a *Vaughn* index of any responsive records withheld under any claimed exemption;

f. Enjoin Defendant from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA request;

g. Maintain jurisdiction over this action until Defendant complies with FOIA and all orders of this Court;

h. Grant Plaintiff an award of attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and

- i. Grant Plaintiff such other relief as the Court deems just and proper.

Dated: January 25, 2022

SIRI & GLIMSTAD LLP

/s/ Colin M. Farnsworth

Aaron Siri, Bar No. 4321790

(*pro hac vice* to be filed)

Elizabeth A. Brehm, NY Bar No. 4660353

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