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 -and- U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue SW Washington, DC 20201 Defendants.	Civil Action No. 1:24-cv-1555

COMPLAINT

Plaintiff Informed Consent Action Network ("**ICAN**" or "**Plaintiff**") brings this action against defendants Food and Drug Administration ("**FDA**") and the United States Department of Health and Human Services ("**HHS**" together with FDA "**Defendants**") 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 5 U.S.C. § 522(a)(4)(B) and 28 U.S.C. § 1331.

PARTIES

3. Plaintiff ICAN is a not-for-profit organization formed and existing under the laws of the state of Texas with its principal office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705. Plaintiff is in good standing with the Texas Secretary of State.

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). FDA has possession, custody, and control of records to which Plaintiff seeks access.

5. Defendant HHS is an agency within the Executive Branch of the United States Government. HHS 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.

STATEMENT OF FACTS

6. On December 27, 2023, Plaintiff sent a FOIA request to FDA seeking copies of the following records:

> All clinical trial documents relied upon by FDA to approve GlaxoSmithKline's BOOSTRIX (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed).

(**Exhibit 1**.)

7. Defendant FDA acknowledged Plaintiff's FOIA request on December 29, 2023 and the request was assigned 2023-11544. (**Exhibit 2**.)

8. As of the date of this Complaint, Defendants have failed to: (i) determine whether to comply with the request; (ii) notify Plaintiff of any such determination or the reasons therefor; or (iii) advise Plaintiff of the right to appeal any adverse determination other than denial of expedited processing.

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

9. Plaintiff realleges the previous paragraphs as if fully stated herein.

10. Defendants are in violation of FOIA.

11. Defendants were required to make a final determination on Plaintiff's request no later than twenty (20) business days from acknowledgement of the request. Because Defendants failed to make a final determination on Plaintiff's request within the time limits set by FOIA, Plaintiff is deemed to have exhausted its administrative appeal remedies.

12. Plaintiff is being irreparably harmed by reason of Defendants' violation of FOIA and Plaintiff will continue to be irreparably harmed unless Defendants are compelled to comply with the law.

13. Plaintiff has no adequate remedy at law.

COUNT II
FAILURE TO PROVIDE AN ESTIMATED COMPLETION DATE
(VIOLATION OF FOIA, 5 U.S.C. § 552)

14. Plaintiff realleges the previous paragraphs as if fully stated herein.

15. Defendants are in violation of FOIA.

16. Defendant's never provided an estimated date on which the agency would complete its action on the request.

COUNT III
IMPROPER WITHHOLDING OF INFORMATION AND DATA
(VIOLATION OF FOIA, 5 U.S.C. § 552)

17. Plaintiff realleges the previous paragraphs as if fully stated herein.

18. Defendants have failed to establish that they adequately applied an exemption to withheld information and data.

19. Defendants are in violation of FOIA.

COUNT IV
FAILURE TO ESTABLISH AN ADEQUATE SEARCH
(VIOLATION OF FOIA, 5 U.S.C. § 552)

20. Plaintiff realleges the previous paragraphs as if fully stated herein.

21. Defendants have failed to establish that they adequately searched for responsive records.

22. Defendants are in violation of FOIA.

COUNT V
ENTITLEMENT TO WAIVER OF SEARCH FEES

23. Plaintiff realleges the previous paragraphs as if fully stated herein.

24. Defendants are in violation of FOIA.

25. Plaintiff sought a waiver of fees. Defendants failed, within 20 days, to produce the requested records and otherwise failed to comply with the statutory requirements of 5 U.S.C. § 522 within the time limits set forth therein.

26. Plaintiff is entitled to a waiver of fees pursuant to 5 U.S.C. § 552(a)(4)(A)(viii).

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

a. Declare that Defendants' current and continued delay in processing Plaintiff's FOIA Request is unlawful under FOIA;

b. Order Defendants to conduct searches for any and all records responsive to Plaintiff's FOIA request and demonstrate that they employed search methods reasonably likely to lead to the discovery of records responsive to Plaintiff's FOIA request;

c. Order Defendants 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;

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

e. Maintain jurisdiction over this action until Defendants comply with FOIA and all orders of this Court;

f. 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);

g. Grant Plaintiff a fee waiver pursuant to 5 U.S.C. § 552(a)(4)(A)(viii); and

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

Dated: May 25, 2024

SIRI & GLIMSTAD LLP

/s/ Allison R. Lucas

Allison R. Lucas, DC Bar No. MI0105
220 West Congress Street
2nd Floor
Detroit, MI 48226
Tel: (240) 732-6737
alucas@sirillp.com

Elizabeth A. Brehm, DC Bar No. NY0532
745 Fifth Ave
Suite 500
New York, New York 10151
Tel: (240) 732-6737
ebrehm@sirillp.com