

**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-451

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 5 U.S.C. § 522(a)(4)(B).

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. 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.

STATEMENT OF FACTS

5. On November 1, 2021, Plaintiff sent a FOIA request to FDA seeking copies of the following records:

All documents related to dose determination for the Pfizer COVID-19 vaccine, including documents reflecting the process(es) used to determine dose and the data used to support the process(es). These documents may include, but should not be limited to, communications, meeting recordings, transcripts, or minutes wherein dose determination was discussed and/or decided.

(Exhibit 1.)

6. That same day, Plaintiff received notice via email that its FOIA request was received. The notice also included the following statement:

FOIA staff will review your request to determine whether it has sufficient information to be processed; if so, you will receive another email as a formal acknowledgement of your request, with a control number for your request. If your request is not sufficiently described, or if there are any other deficiencies with your submission, FOIA staff will contact you via telephone or email.

(Exhibit 2.)

7. On November 3, 2021, FDA sent a formal acknowledgment of Plaintiff's request, and indicated that it "may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA." **(Exhibit 3.)**

8. After not receiving any communication from Defendant for over three months, on March 18, 2022, Plaintiff emailed FDA pursuant to 5 U.S.C. § 552 (a)(7)(B)(ii) and requested an estimated date on which the agency would complete its action on the request. **(Exhibit 4 at 2.)**

9. On March 22, 2022, the agency responded to Plaintiff's inquiry regarding the estimated completion date, and asked the following questions: "In order to provide you with the most accurate estimate, can you please provide me with some additional clarification? . . . Is the scope of your request limited to the original approval of COMIRNATY (approval August 23, 2021) regarding individuals 16 years of age and older?" (**Exhibit 4** at 1.)

10. On May 13, 2022, Plaintiff responded by stating "[o]ur request is limited to the original emergency use authorization of the Pfizer/Biotech vaccine." (**Exhibit 4** at 1.)

11. As of the date of this Complaint, Defendant has failed to: (i) determine whether to comply with the request; (ii) notify Plaintiff of any such determination or the reasons therefor; (iii) advise Plaintiff of the right to appeal any adverse determination; or (iv) produce the requested records or otherwise demonstrate that the requested records are exempt from production.

12. Moreover, Defendant has failed to provide Plaintiff with an estimated date on which the agency will complete action on the request.

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

13. Plaintiff realleges paragraphs 1 through 12 as if fully stated herein.

14. Defendant is in violation of FOIA.

15. Defendant was required to make a final determination on Plaintiff's request no later than December 15, 2021. Because Defendant 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.

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

16. Plaintiff realleges paragraphs 1 through 15 as if fully stated herein.
17. Defendant is in violation of FOIA.
18. Despite Plaintiff's request for an estimated date on which the agency would complete its action on the request, the agency never provided one.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

- a. Declare that Defendant's current and continued delay in processing Plaintiff's FOIA Request is unlawful under FOIA;
- b. 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 Plaintiff's FOIA request;
- c. 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;
- d. Enjoin Defendant from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA request;
- e. Maintain jurisdiction over this action until Defendant complies 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); and
- g. Grant Plaintiff such other relief as the Court deems just and proper.

Dated: February 17, 2023

SIRI & GLIMSTAD LLP

/s/ Colin Farnsworth

Aaron Siri, Bar No. 4321790

(pro hac vice to be filed)

Elizabeth A. Brehm, NY Bar No. 4660353

(pro hac vice to be filed)

Colin M. Farnsworth, DC Bar ID OR0022

Siri & Glimstad LLP

745 Fifth Avenue, Suite 500

New York, New York 10151

Tel: (212) 532-1091

aaron@sirillp.com

ebrehm@sirillp.com

cfarnsworth@sirillp.com