IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JUDICIAL WATCH, INC., 425 Third Street SW, Suite 800 Washington, DC 20024, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue SW Washington, DC 20201, Defendant.	)	Civil Action No.

COMPLAINT

Plaintiff Judicial Watch, Inc. ("Plaintiff") brings this action against Defendant U.S. Department of Health and Human Services ("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(e).

PARTIES

3. Plaintiff Judicial Watch, Inc. is a not-for-profit, educational organization incorporated under the laws of the District of Columbia and headquartered at 425 Third Street SW, Suite 800, Washington, DC 20024. Plaintiff seeks to promote transparency, integrity, and accountability in government and fidelity to the rule of law. As part of its mission, Plaintiff

regularly requests records from federal agencies, analyzes the responses it receives, and disseminates its findings and the records to the American public to inform them about "what their government is up to."

4. Defendant U.S. Department of Health and Human Services is an agency of the U.S. Government and is headquartered at 200 Independence Avenue SW, Washington, DC 20201. Defendant has possession, custody, and control of records to which Plaintiff seeks access.

STATEMENT OF FACTS

5. On February 24, 2022, Plaintiff submitted three FOIA requests via the web portal to the Food and Drug Administration ("FDA"), a component of Defendant. The first request sought the following records:

1. All emails and written correspondence, both internal and with the manufacturers, of Mifeprex and Mifepristone regarding review and acceptance of those drugs' drug stability and dissolution test results.

2. Reports from all FDA inspections and assessments of DANCO and GenBio manufacturing facilities, and assessment of compliance with applicable laws and regulations.

The time frame of the request for was identified as "January 24, 1995 to present."

6. The second request sought the following records:

1. Investigational New Drug Applications and related materials for the drug Mifeprex and its generic equivalent, Mifepristone.

2. New Drug Applications and related materials for the drug Mifeprex and its generic equivalent, Mifepristone.

The time frame of the request was January 24, 1990 to present.

7. The third request sought the following records:

1. Stability test results for the drug Mifeprex and its generic equivalent, Mifepristone, pursuant to ICH requirements, including but not limited to,

records reflecting long-term stability, and accelerated and forced degradation results.

2. Drug Product Transportation Stability studies for the drug Mifeprex and its generic equivalent, Mifepristone, including but not limited to, the expiry and temperature statements.

3. Dissolution test results for the drug Mifeprex and its generic equivalent, Mifepristone.

The time frame of the request for was identified as "January 24, 1995 to present."

8. FDA acknowledged each request on March 1, 2022 and referred to the 10-day extension to reply.

9. 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.

COUNT I
(Violation of FOIA, 5 U.S.C. § 552)

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

11. Defendant is in violation of FOIA.

12. Plaintiff is being irreparably harmed by Defendant's violation of FOIA, and Plaintiff will continue to be irreparably harmed unless Defendant is compelled to comply with the law.

13. Plaintiff has no adequate remedy at law.

14. To trigger FOIA's administrative exhaustion requirement, Defendant was required to make final determinations on Plaintiff's request by April 12, 2022, at the latest.

Because Defendant failed to make final determinations on Plaintiff's requests/appeal within the time limits set by FOIA, Plaintiff is deemed to have exhausted its administrative appeal remedies.

WHEREFORE, Plaintiff respectfully requests that the Court: (1) order Defendant to conduct a search for any and all records responsive to Plaintiff's FOIA requests and demonstrate that it employed search methods reasonably likely to lead to the discovery of records responsive to Plaintiff's FOIA requests; (2) order Defendant to produce, by a date certain, any and all non-exempt records responsive to Plaintiff's FOIA requests and *Vaughn* indices of any responsive records withheld under claim of exemption; (3) enjoin Defendant from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA requests; (4) 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 (5) grant Plaintiff such other relief as the Court deems just and proper.

Dated: October 17, 2022

Respectfully submitted,

/s/ Meredith Di Liberto

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