September 19, 2025

Food and Drug Administration
Division of Headquarters Freedom of Information
Office of Disclosure, Information, Governance and Accessibility, ODIGA
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Request Under the Freedom of Information Act

To Whom It May Concern:

This letter constitutes a request made pursuant to the Freedom of Information Act, 5 U.S.C. § 552, and implementing regulations of the U.S. Food and Drug Administration ("FDA"), 21 C.F.R. Part 20.

On June 2, 2025, FDA announced its launch of Elsa, a generative artificial intelligence (AI) tool that was designated to be used by FDA employees, including scientific reviewers.[1] In FDA's press release, it stated "[t]he agency is already using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets."[2] It also stated that Elsa does not "train on data submitted by regulated industry, safeguarding the sensitive research and data handled."[3] However, users of the tool have reportedly explained that it is unreliable and sometimes "hallucinates" and cites studies that do not exist, which has been a problem with AI tools writ large.[4] There is also concern that there is not sufficient oversight of Elsa to understand what guardrails exist, such as human review of information generated by Elsa, and ensure that regulatory decisions are accurate and based on good information and science.[5] Elsa is based on the AI company Anthropic's Claude large language model ("LLM",) which was developed by Deloitte; Elsa has cost taxpayers $13.8 million to develop the original database and an additional $14.7 million to scale across FDA.[6]

In parallel, on June 3, 2025, FDA Commissioner Dr. Makary replied to a letter from Senator Josh Hawley, committing to "conducting a review of mifepristone" based on a newly release publication from the Ethics and Public Policy Center about mifepristone.[7] The

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[1] FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People, FOOD & DRUG ADMIN., Jun. 2, 2025, https://www.fda.gov/news-events/press-announcements/fda-launches-agency-wide-ai-tool-optimize-performance-american-people.
[2] *Id*.
[3] *Id*.
[4] Chris Mazzolini and Mike Hollan, *FDA's Elsa AI Tool Raises Accuracy and Oversight Concerns*, APP. CLIN. TRIALS, Jul. 23, 2025, https://www.appliedclinicaltrialsonline.com/view/fda-elsa-ai-tool-raises-accuracy-and-oversight-concerns; Sarah Owermohle, FDA's artificial intelligence is supposed to revolutionize drug approvals. It's making up studies, CNN, Jul. 23, 2025, https://www.cnn.com/2025/07/23/politics/fda-ai-elsa-drug-regulation-makary.
[5] *Id.*
[6] Beth Mole, *FDA rushed out agency-wide AI tool—it's not going well*, ARS TECHNICA, Jun. 5, 2025, https://arstechnica.com/health/2025/06/fda-rushed-out-agency-wide-ai-tool-its-not-going-well/.
[7] Josh Hawley (@HawleyMO), X (June 2, 2025, 8:27 PM), https://x.com/HawleyMO/status/1929696353010987013; Alejandra O'Connell-Domenech, *FDA Commissioner*

publication does not meet scientific review standards: neither of its authors, Jamie Bryan Hall and Ryan T. Anderson, have clinical experience or medical training; the publication was not published in a peer-reviewed scientific journal; and the authors did not disclose data sources, meaning that the findings cannot be reproduced or verified.[8]

The Center for Reproductive Rights ("Center") seeks to better understand FDA's use of Elsa generally as well as specifically as it relates to any FDA review of mifepristone. Releasing this information is vital to the public interest in order to increase transparency about the use of AI by FDA in drug reviews, including related to mifepristone.

Records Requested

Please provide all responsive records from January 20, 2025, through the date the search is conducted. As used herein, "records" means all records as defined in 22 C.F.R. § 171.1(b). Additionally, as used herein, any reference to FDA encompasses all district offices (both current and past), as well as the central offices located in Silver Spring, Maryland. Please note that "communications" requested include, but are not limited to, e-mails, messaging platforms (including, but not limited to Signal, Slack, GChat or Google Hangouts, Lync, Skype, X (formerly Twitter) direct messages, Facebook messages, Truth Social messages, WhatsApp, Telegram, or Parler), and communications and relevant materials that may have been distributed via personal phones or devices.

We request the following to be produced within twenty business days:

1. Any and all contracts between FDA and Deloitte, including its parent companies, subsidiaries and/or entities in the Deloitte network, as applicable, for the services rendered to develop Elsa for the Agency;

2. Any and all contracts between FDA and Anthropic including its parent companies and/or subsidiaries, as applicable, for the use of Elsa by the Agency, including but not limited to agreements that cover the data privacy and data security requirements for the use of Elsa by the Agency;

3. All data, records, documents, guidance, memoranda, communications meeting notices, meeting agendas, informational materials, draft legislation, draft rules, talking points, reports, disclosures, or other documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor related to FDA employees' and contractors' use of Elsa, including, but not limited to, use of Elsa for drug application reviews, drug safety reviews, and data analysis; and

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Pledges to Investigate Mifepristone, THE HILL, Jun. 3, 2025, https://thehill.com/policy/healthcare/5330774-marty-makary-fda-mifepristone-review/.

[8] Jamie Bryan Hall and Ryan T. Anderson, THE ABORTION PILL HARMS WOMEN: INSURANCE DATA REVEALS ONE IN TEN PATIENTS EXPERIENCES A SERIOUS ADVERSE EVENT (2025); UCLA Law Center for Reproductive Health, Law, and Policy and UCSF Advancing New Standards in Reproductive Health, Letter to FDA: Reproductive Health Researchers' Comment (Aug. 27, 2025), FDA-2025-P-1576, https://www.regulations.gov/comment/FDA-2025-P-1576-0151.

4. All data, records, documents, guidance, memoranda, communications, meeting notices, meeting agendas, informational materials, draft legislation, draft rules, talking points, reports, disclosures, or other documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor about the use of Elsa for any review of mifepristone.

The Center seeks all responsive records regardless of format, medium, or physical characteristics. In conducting your search, please understand the terms "record," "document," and "information" in their broadest sense, to include any written, typed, recorded, graphic, printed, or audio material of any kind. We seek records of any kind, including electronic records, audiotapes, videotapes, and photographs, as well as letters, emails, facsimiles, telephone messages, voice mail messages and transcripts, notes, or minutes of any meetings, telephone conversations or discussions. Our request includes any attachments to these records. No category of material should be omitted from search, collection, and production.

In addition to the records requested above, the Center also requests records describing the processing of this request, including records sufficient to identify search terms used, locations and custodians searched, and any tracking sheets used to track the processing of this request. If the FDA uses FOIA questionnaires or certifications completed by individual custodians or components to determine whether they possess responsive materials or to describe how they conducted searches, we also request any such records prepared in connection with the processing of this request.

Please search all records regarding agency business. You may not exclude searches of files or emails in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA. It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; the Center has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, through negligence or willfulness, failed to meet their obligations.

Please note that in conducting a "reasonable search" as required by law, you must employ the most up-to-date technologies and tools available, in addition to searches by individual custodians likely to have responsive information. Recent technology may have rendered your agency's prior FOIA practices unreasonable. In light of the government-wide requirements to manage information electronically by the end of 2016, it is no longer reasonable to rely exclusively on custodian-driven searches. Furthermore, agencies, including the HHS Office of the Assistant Secretary for Health, that have adopted the National Archives and Records Agency Capstone program, or similar policies, now maintain emails in a form that is reasonably likely to be more complete than individual custodians' files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools would capture that email under Capstone.

Accordingly, the Center requests that the FDA use the most up-to-date technologies to search for responsive information and take steps to ensure that the most complete repositories of information are searched. The Center is available to work with you to craft appropriate search

terms. However, custodian searches are still required; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

We request that you produce all responsive materials in their entirety; however, should you determine the materials contain information which falls within the statutory exemptions provided in 5 U.S.C. § 552 or 22 C.F.R. § 171.11, we request the information be reviewed for possible discretionary disclosure. We furthermore request that all reasonably segregable portions of the exempt material be provided. We request that any deleted material be described in detail, and that you specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies in this instance. Please separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements will be helpful in deciding whether to appeal an adverse determination.

Under the FOIA Improvement Act of 2016, agencies must adopt a presumption of disclosure, withholding information "only if . . . disclosure would harm an interest protected by an exemption" or "disclosure is prohibited by law." If it is your position that any portion of the requested records is exempt from disclosure, the Center requests that you provide an index of those documents as required under *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974). As you are aware, a *Vaughn* index must describe each document claimed as exempt with sufficient specificity "to permit a reasoned judgment as to whether the material is actually exempt under FOIA."[9] Moreover, the *Vaughn* index "must describe each document or portion thereof withheld, and for each withholding it must discuss the consequences of disclosing the sought-after information."[10] Further, "the withholding agency must supply 'a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply.'"[11]

You should institute a preservation hold on information responsive to this request. The Center intends to pursue all legal avenues to enforce its right of access under FOIA, including litigation if necessary. Accordingly, your agency is on notice that litigation is reasonably foreseeable.

To ensure that this request is properly construed, that searches are conducted in an adequate but efficient manner, and that extraneous costs are not incurred, the Center welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, the Center and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Waiver or Limitation of Fees

Pursuant to 5 U.S.C. § 552(a)(4)(A)(iii), documents are required to be provided to requesters without any charge or at reduced fees "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." We

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[9] *Founding Church of Scientology v. Bell*, 603 F. 2d 945, 949 (D.C. Cir. 1979).
[10] *King v. U.S. Dep't of Just*., 830 F.2d 210, 223-24 (D.C. Cir. 1987).
[11] *Id.* at 224.

request a waiver (or, in the alternative, a reduction) of all fees because disclosure of the information would be in the public interest by contributing significantly to the public understanding of the hiring processes in place at FDA.

Founded in 1992, the Center is the only global legal advocacy organization dedicated to reproductive rights, and its litigation and advocacy has played a key role in expanding access to reproductive health care around the world. The Center uses information gathered, and its analysis of information gathered, to educate the public through reports, briefing papers, fact sheets, periodicals, articles, blog posts, and other educational materials. Likewise, the Center also makes the materials gathered available on its public website and promotes their availability on social media platforms, such as Facebook, X (formerly known as Twitter), and Instagram. The Center receives hundreds of thousands of website page views, monthly, and publishes newsletters for public dissemination. Thus, the Center has demonstrated commitment to the public disclosure of documents and creation of editorial content.

The Center does not make this request for commercial use. 45 C.F.R. § 5.54(b)(3). As a 501(c)(3) nonprofit organization, the Center does not have a commercial purpose, and the release of the information requested is not in the organization's financial interest. Accordingly, the Center qualifies for a fee waiver.

In the event that you determine you are unable to waive the fees, please provide us with prior notice if the total fees authorized will exceed $200 so that we can discuss arrangements.

Conclusion

The Center looks forward to working with your agency on this request. Thank you for your prompt attention to this matter.

With respect to the form of production, *see* 5 U.S.C. § 552(a)(3)(B), the Center requests that responsive materials be provided electronically by email or in PDF or TIF format on a USB drive. Please send any responsive material being provided and acknowledgement of receipt of this request to:

Liz McCaman Taylor
c/o Julia Long
Center for Reproductive Rights
1600 K Street, NW
Washington, DC 20006
Phone: (202) 524-5533
Email: ltaylor@reprorights.org

If it will accelerate release of responsive records, please also provide responsive material on a rolling basis.

If you do not understand any part of this request, have any questions, or foresee any problems in fully releasing the requested records, please contact Liz McCaman Taylor at (202) 524-5533 if you have any questions. Thank you for your assistance.

Sincerely,

Liz McCaman Taylor