AMERICAN OVERSIGHT

March 19, 2026

VIA ONLINE PORTAL

Food and Drug Administration
Division of Headquarters Freedom of Information
Office of Disclosure, Information, Governance and Accessibility, ODIGA
5630 Fishers Ln., Rm. 1035
Rockville, MD 20857
Via Online Portal

Re: Freedom of Information Act Request

Dear FOIA Officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, American Oversight makes the following request for records.

In June 2025, the Food and Drug Administration (FDA) announced the Commissioner's National Priority Voucher (CNPV) pilot program as a way to accelerate the review of products with the potential to address key national priorities.[1] For example, the CNPV program utilizes an "ultra-fast timeline"[2] to review a company's selected product if the company has agreed to increase affordability, domesticate manufacturing, or address an unmet public health need.[3] FDA awarded 18 vouchers in 2025 for a variety of products related to infertility, lung cancer, blindness, sickle cell disease, and obesity, among other health conditions.[4] One product received FDA approval via the CNPV program in December 2025, and one product was rejected in February 2026.[5] FDA continues to

[1] *See* Press Release, *FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests*, June 17, 2025, https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests.
[2] *See* Fact Sheet, *Commissioner's National Priority Voucher (CNPV) Pilot Program*, https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program (last visited Mar. 18, 2026).
[3] *See* Press Release, *FDA Awards Second Batch of National Priority Vouchers*, Nov. 6, 2025, https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers.
[4] *See, e.g.*, Press Release, *FDA Awards First-Ever National Priority Vouchers to Nine Sponsors*, Oct. 16, 2025, https://www.fda.gov/news-events/press-announcements/fda-awards-first-ever-national-priority-vouchers-nine-sponsors; Press Release, *FDA Awards Second Batch of National Priority Vouchers*, Nov. 6, 2025, https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers.
[5] *See* Press Release, FDA Grants Two National Priority Vouchers, Dec. 19, 2025, https://www.fda.gov/news-events/press-announcements/fda-grants-two-national-

accept requests to participate in the CNPV program and will award a limited number of vouchers on a rolling basis.[6] American Oversight seeks records with the potential to shed light on this matter, including how FDA is exploring pathways to accelerate the review and approval of innovative treatments while ensuring the safety and efficacy of these therapies.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

> **For all parts of this request, please provide all responsive records created, issued, or in effect from May 17, 2025, through the date the search is conducted.**
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> 1. All supporting documentation or evidence relied upon by FDA to develop the following CNPV national health priorities:
>   a. addressing a U.S. public health crisis;
>   b. delivering more innovative cures for the American people;
>   c. addressing a large unmet medical need;
>   d. onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency; and
>   e. increasing affordability.[7]
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> 2. All formal and informal directives, guidance, protocols, and/or policies created by FDA and provided to internal stakeholders (e.g., offices, centers, divisions) regarding the CNPV program.
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> 3. All formal and informal directives, guidance, protocols, and/or policies issued by FDA to external stakeholders regarding the CNPV program.
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> 4. A complete list of all members, experts, consultants, and/or officials serving on the CNPV Pilot Advisory Group.

priority-vouchers; Tristan Manalac, "FDA Rejects Disc's Rare Blood Disease Drug Amid Reports of Prasad's Skepticism," BioSpace, Feb. 16, 2026, https://www.biospace.com/fda/fda-rejects-discs-rare-blood-disease-drug-amid-reports-of-prasads-skepticism.

[6] *See* Commissioner's National Priority Voucher (CNPV) Pilot Program Submission, https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program/commissioners-national-priority-voucher-cnpv-pilot-program-submission (last visited Mar. 18, 2026).

[7] For further identifying information, *see supra* note 1.

5. The "specific criteria" used by the FDA Commissioner to "make the vouchers available to companies," as mentioned in FDA's announcement of the CNPV program in June 2025.[8]

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government."[9] The public has a significant interest in how the federal government is working to deliver more cures and meaningful treatments that address unmet public health needs and ongoing health crises.[10] Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including how FDA is ensuring that efforts to fast-track the approval process for new drugs, treatments, and therapeutics do not compromise the scientific integrity of the review process. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

This request "is not primarily in the commercial interest of the requester."[11] In fact, as a 501(c)(3) nonprofit, American Oversight does not have a commercial purpose, and the release of the information requested is not in American Oversight's commercial interest. American Oversight's mission is to promote transparency in government, to educate the public about government activities, and to ensure the accountability of government officials. American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. American Oversight

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[8] *See* Press Release, *FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests*, June 17, 2025, https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests.

[9] 5 U.S.C. § 552(a)(4)(A)(iii).

[10] *See* Lizzy Lawrence, *FDA Commissioner Marty Makary Tries to Soothe Staff Concerns Over Voucher Program*, Stat News, Feb. 3, 2026, https://www.statnews.com/2026/02/03/fda-commissioner-marty-makary-addresses-staff-concerns-drug-voucher-program/.

[11] 5 U.S.C. § 552(a)(4)(A)(iii).

also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and X (formerly Twitter).[12]

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through regular substantive analyses posted to its website.[13] Examples reflecting this commitment include the posting of records related to the first Trump Administration's contacts with Ukraine and analyses of those contacts;[14] posting records and editorial content about the federal government's response to the COVID-19 pandemic;[15] posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the first Trump administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal;[16] the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers;[17] and posting records and analysis of federal officials' use of taxpayer dollars to charter private aircraft or use government planes for unofficial business.[18]

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[12] American Oversight currently has approximately 16,000 followers on Facebook and 94,900 followers on X (formerly Twitter). American Oversight, Facebook, https://www.facebook.com/weareoversight/ (last visited Mar. 18, 2026); American Oversight (@weareoversight), X (formerly Twitter), https://x.com/weareoversight (last visited Mar. 18, 2026).

[13] *See generally Our Latest*, American Oversight, https://www.americanoversight.org/blog.

[14] *The Trump Administration's Contacts with Ukraine*, American Oversight, https://www.americanoversight.org/investigation/the-trump-administrations-contacts-with-ukraine.

[15] *See generally The Trump Administration's Response to Coronavirus*, American Oversight, https://www.americanoversight.org/investigation/the-trump-administrations-response-to-coronavirus; *see, e.g.*, *CDC Calendars from 2018 and 2019: Pandemic-Related Briefings and Meetings*, American Oversight, https://www.americanoversight.org/cdc-calendars-from-2018-and-2019-pandemic-related-briefings-and-meetings.

[16] *See generally Audit the Wall*, American Oversight, https://www.americanoversight.org/investigation/audit-the-wall; *see, e.g.*, *Audit the Wall: No Plans, No Funding, No Timeline, No Wall*, American Oversight, https://americanoversight.org/audit-the-wall-no-plans-funding-or-timeline-and-no-wall/.

[17] *DOJ Records Relating to Solicitor General Noel Francisco's Recusal*, American Oversight, https://www.documentcloud.org/documents/25544090-doj-records-relating-to-solicitor-general-noel-franciscos-recusal-american-oversight; *Francisco & the Travel Ban: What We Learned from the DOJ Documents*, American Oversight, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

[18] *See generally Swamp Airlines: Chartered Jets at Taxpayer Expense*, American Oversight, https://www.americanoversight.org/investigation/swamp-airlines-private-jets-taxpayer-expense; *see, e.g.*, *New Information on Pompeo's 2017 Trips to His Home State*, American Oversight, https://www.americanoversight.org/new-information-on-pompeos-2017-trips-to-his-home-state.

Accordingly, American Oversight qualifies for a fee waiver.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

- Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics. For instance, if the request seeks "communications," please search all locations likely to contain communications, including relevant hard-copy files, correspondence files, appropriate locations on hard drives and shared drives, emails, and shared messages systems such as Slack.

- In conducting your search, please understand the terms "record," "document," and "information" in their broadest sense, to include any written, typed or printed material of any kind. We seek records of any kind, including electronic records, letters, emails, facsimiles, and transcripts, notes, or minutes of any meetings, telephone conversations, or discussions.

- Our request for records includes any attachments to those records or other materials enclosed with those records when they were previously transmitted. To the extent that an email is responsive to our request, our request includes all prior messages sent or received in that email chain, as well as any attachments to the email.

- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices 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.[19] 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; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.[20]

- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-

[19] *See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, 827 F.3d 145, 149–50 (D.C. Cir. 2016); *cf. Judicial Watch, Inc. v. Kerry*, 844 F.3d 952, 955–56 (D.C. Cir. 2016).
[20] *See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

wide requirements to manage agency information electronically,[21] and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.

- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight. American Oversight 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, American Oversight and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

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[21] Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency on this request. If you do not understand any part of this request, please contact David Kronig at foia@americanoversight.org or (202) 897-3915. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.

Sincerely,

/s/ David Kronig
David Kronig
on behalf of
American Oversight