



July 27, 2020

VIA ONLINE PORTAL

Sarah Kotler
FOIA Officer
Food and Drug Administration
5630 Fishers Lane, Room 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 particular, American Oversight seeks records that will inform the American public of how senior government officials are choosing to spend taxpayer dollars.

Requested Records

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

All calendars or calendar entries for any of the following individuals from January 1, 2020, to the date a search is conducted, including any calendars maintained on their behalf, such as calendars maintained by an administrative assistant or scheduler.

1. Stephen Hahn, Commissioner
2. Amy Abernethy, Principal Deputy Commissioner
3. Keagan Lenihan, Chief of Staff
4. Peter Marks, Director, Center for Biologics Evaluation and Research
5. Janet Woodcock, Director, Center for Drug Evaluation and Research
6. Stacy Amin, General Counsel

For calendar entries created in Outlook or similar programs, the documents should be produced in “memo” form to include all invitees, any notes, and all attachments. Please do not limit your search to Outlook calendars—we request the production of any calendar—paper or electronic, whether on government-issued or



personal devices—used to track or coordinate how these individuals allocate their time on agency business.

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 primarily and fundamentally 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.”¹ The public has a significant interest in the protection of public health. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including how leadership allocates their time and resources, particularly during a public health crisis. 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 primarily and fundamentally for non-commercial purposes.² 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 financial 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 also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter.³

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website.⁴ Examples reflecting this commitment to the public disclosure of

¹ 5 U.S.C. § 552(a)(4)(A)(iii).

² See 5 U.S.C. § 552(a)(4)(A)(iii).

³ American Oversight currently has approximately 15,600 page likes on Facebook and 104,300 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited July 23, 2020); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited July 23, 2020).

⁴ News, AMERICAN OVERSIGHT, <https://www.americanoversight.org/blog>.

documents and the creation of editorial content include 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;⁵ posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal;⁶ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis;⁷ posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia;⁸ and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.⁹

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.

⁵ *DOJ Records Relating to Solicitor General Noel Francisco's Recusal*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance>; *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>.

⁶ *See generally Audit the Wall*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/investigation/audit-the-wall>; *see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall>.

⁷ *Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/documents-reveal-ben-carson-jr-s-attempts-to-use-his-influence-at-hud-to-help-his-business>.

⁸ *Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia>.

⁹ *Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/sessions-letter>.

- Our request for records includes any attachments to those records or other materials enclosed with those records when they were previously transmitted. 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.¹⁰ 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.¹¹
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,¹² 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

¹⁰ 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).

¹¹ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹² 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>.

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 to discuss this request. 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.

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 Christine Monahan at foia@americanoversight.org or 202.869.5244. 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,

A handwritten signature in blue ink, appearing to read "Austin R. Evers", with a long horizontal flourish extending to the left.

Austin R. Evers
Executive Director
American Oversight