U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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June 25, 2024

The Honorable Bernard Sanders
Chair
The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Food and Drug Administration: Office of the Executive Secretariat's Processes for Correspondence Were Consistent with Selected Internal Control Standards

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, is responsible for protecting public health. Among other things, FDA helps ensure the safety, efficacy, and security of human medical products marketed in the United States and the safety of more than 80 percent of the U.S. food supply. Within FDA, the Office of the Executive Secretariat (OES) controls and processes all public correspondence directed to FDA's Commissioner. It also has the following responsibilities:

- advises FDA's Commissioner on FDA-wide initiatives,
- coordinates communication across FDA and between FDA's Commissioner and other federal entities, and
- manages briefing materials and supporting documentation for recommendations presented for the Commissioner's consideration.

The Food and Drug Omnibus Reform Act of 2022—enacted December 29, 2022, as part of the Consolidated Appropriations Act, 2023—includes a provision that GAO assess OES's policies and practices with respect to the receipt, tracking, managing, and prioritization of correspondence.[1] This report assesses the extent to which OES's policies, procedures, and practices for receiving, tracking, managing, and prioritizing correspondence are consistent with

[1]Pub. L. No. 117-328, div. FF, tit. III, subtit. F, § 3628(c), 136 Stat. 4459, 5891 (Dec. 29, 2022). While the provision states that GAO is to assess the policies and practices of OES's Division of Executive Operations, in this report we refer primarily to OES as the entity that handles correspondence directed to FDA's Commissioner rather than the Division of Executive Operations (DEO). OES officials told us that DEO and OES are the same entity.

selected internal control standards. For the purposes of our review, policies and procedures refer to written documents such as the agency's staff manual guide or standard operating procedures. Practices refer to actions agency officials take to conduct their work, including how they follow policies and procedures, such as how information is entered into an information management system.

To address this objective, we reviewed policies and procedures for handling correspondence in OES. For purposes of our review, we defined correspondence as including email, postal mail, and communications delivered by common carrier, such as FedEx or UPS. The correspondence policies and procedures we reviewed included

- FDA's staff manual guide, revised in December 2018;
- OES's standard operating procedures for correspondence analysts, revised in March 2024 and further revised in April 2024; and
- OES's whistleblower process, formalized in January 2023.[2]

We also interviewed OES officials and staff about these correspondence policies and procedures, as well as their practices for handling correspondence. We reviewed position descriptions for correspondence analysts and policy analysts in OES, the user manual for FDA's Agency Information Management System (AIMS), and two reports FDA submitted to Congress in 2023 about OES and FDA's mailroom.[3]

In March 2024, we visited FDA's headquarters at its White Oak campus in Silver Spring, Maryland, to observe a demonstration of how OES staff receive correspondence and log it into AIMS. We developed a data collection instrument to record our observations of OES's practices from the demonstration and compared them with OES's correspondence policies and procedures.

We compared the information obtained from policy and procedure documents, interviews, and the demonstration against selected internal control standards. We considered the functions carried out by OES to manage correspondence and selected the following internal control standards to assess:

- Management should define objectives clearly to enable the identification of risks and define risk tolerances;
- Management should design control activities to achieve objectives and respond to risks;
- Management should implement control activities through policies;

[2]Food and Drug Administration, *Staff Manual Guide 1111.3a (Office of the Executive Secretariat)* (Dec. 14, 2018). FDA Staff Manual Guides are the agency directives that document organizations and functions; delegations of authority; and administrative and program policies, responsibilities, and procedures.

[3]These reports were required by the same statutory section under which we conducted this work. Food and Drug Administration, *Report to Congress: The Mailroom and the Office of the Executive Secretariat FY 2023, Submitted Pursuant to Section 3628 of the Food and Drug Omnibus Reform Act of 2022* (Silver Spring, MD: October 2023); and *Report to Congress: The Mailroom and the Office of the Executive Secretary, Submitted Pursuant to Section 3628 of the Food and Drug Omnibus Reform Act of 2022* (Silver Spring, MD: April 2023).

- Management should identify, analyze, and respond to significant changes that could impact the internal control system; and
- Management should internally communicate the necessary quality information to achieve the entity's objectives.[4]

We conducted this performance audit from January 2024 to June 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

OES's Organizational Structure and Mission

OES is a component of the Office of the Commissioner of Food and Drugs, the head of FDA. Part of OES's role is to work with the relevant FDA centers and offices to ensure that FDA responds appropriately to all correspondence addressed to the Commissioner.

FDA pursues its mission in part through six product centers, each of which regulates a specific type of product.[5] Other FDA components include offices that inspect regulated products, conduct scientific research, share policy expertise, and provide mission support services, among other functions.[6] For example, FDA's Office of the Chief Scientist is responsible for providing strategic leadership, coordination, and expertise to support scientific research.

As of April 2024, OES had 13 staff and two vacant positions (see fig. 1).[7]

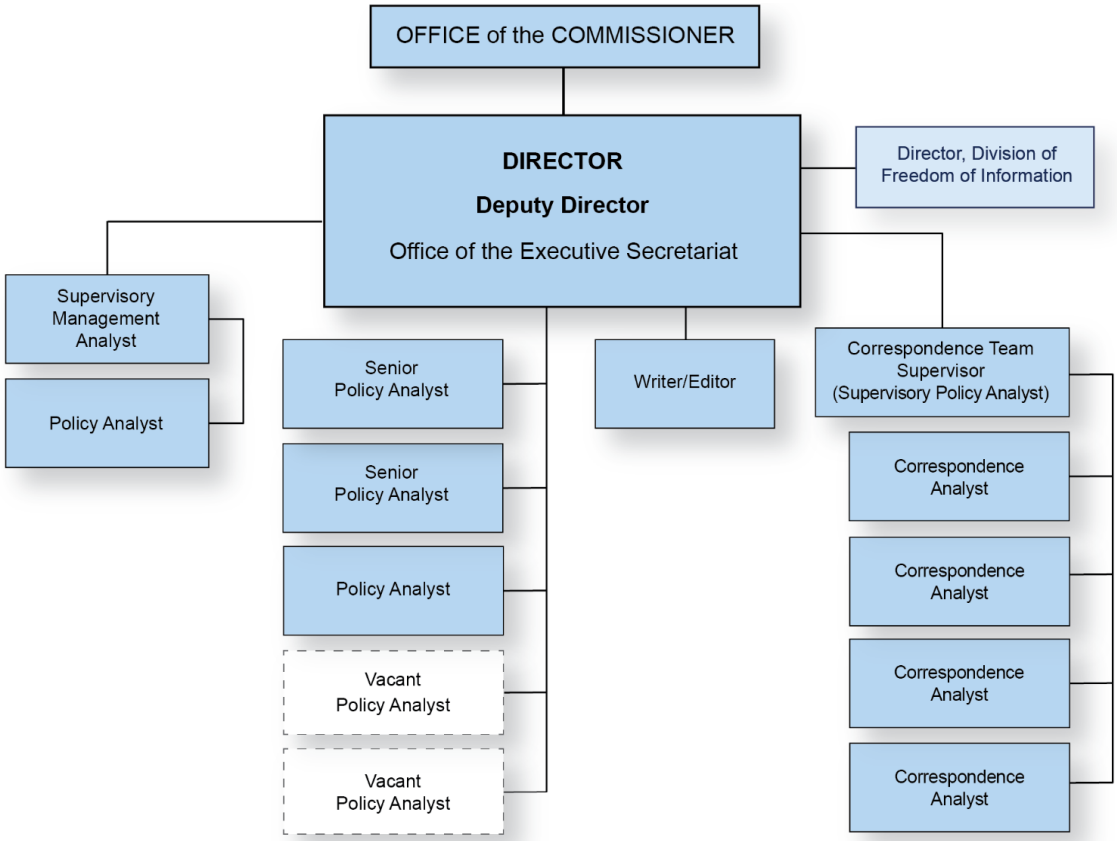
[4]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 10, 2014).

[5]These six product centers are the Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, and the Center for Tobacco Products.

[6]FDA has proposed significant changes to its organizational structure, including creating a unified Human Foods Program and a new structure for the Office of Regulatory Affairs, which is responsible for FDA's field activities, such as inspections. According to congressional testimony by FDA's Commissioner on April 11, 2024, the proposal would also improve how FDA handles whistleblower and consumer complaints. The Commissioner's testimony also stated that FDA transmitted its reorganization package to Congress in March 2024.

[7]These numbers do not include FDA's freedom of information staff.

Figure 1: Organization Chart of the Office of the Executive Secretariat of the Food and Drug Administration



Source: GAO analysis of Department of Health and Human Services, Food and Drug Administration documents and interviews. | GAO-24-107305

Note: For the purposes of our review, we focus on the correspondence role of the Office of the Executive Secretariat.

OES receives correspondence by postal mail, common carrier, and email. According to FDA's October 2023 report to Congress on OES and the FDA mailroom, from January 2023 to July 2023, OES processed 727 pieces of correspondence, excluding congressional correspondence. FDA's mailroom delivers mail and common carrier packages to OES. FDA's mail operating procedures for its White Oak and headquarters buildings state that mail addressed to the Commissioner, Principal Deputy Commissioner, or FDA without a named addressee is to be delivered to OES. OES correspondence analysts receive email sent to the Commissioner's public email address.

Correspondence analysts in OES are responsible for logging incoming email and paper correspondence in AIMS—the information technology system FDA uses for this purpose—and determining how to route correspondence within FDA. They refer some incoming correspondence to FDA centers or offices so they can reply directly to the sender. When the correspondence analyst determines that a piece of correspondence requires a response from the Commissioner, Principal Deputy Commissioner, or the Secretary of Health and Human Services, an OES policy analyst manages the process of developing and reviewing the response.

OES officials told us that they rarely receive correspondence alleging violations of law or disclosing information about safety concerns, such as disclosures from whistleblowers or

confidential sources. The Director of OES stated that OES had received two such complaints from January 2020 through April 2024. OES's standard operating procedures for correspondence, revised in April 2024, state that OES's supervisory correspondence analyst is to send any whistleblower complaints to the appropriate FDA center or office based on the complaint's subject matter. For example, the standard operating procedures state that a complaint from an employee or other informant regarding a manufacturing facility would be assigned to the Office of Regulatory Affairs and shared with the appropriate FDA center or office based on the type of facility.

In May 2024, FDA issued an agency-wide policy on complaints from whistleblowers and confidential sources.[8] The policy assigns responsibility for investigating complaints and deciding on follow-up actions to the six FDA product centers, the Human Foods Program, and the Office of Regulatory Affairs. Other FDA offices, including OES, are to forward any whistleblower or confidential-source complaints they receive to the appropriate investigative office within 2 business days of receipt.

OES's Policies, Procedures, and Practices for Managing Correspondence Were Consistent with Selected Internal Control Standards

We found that OES's policies, procedures, and practices were consistent with selected internal control standards related to defining objectives; identifying, analyzing, and responding to change; designing control activities; implementing control activities; and communicating information internally to achieve objectives. The following are examples of internal controls OES had in place for managing correspondence:

Internal control standard: Management should define objectives clearly to enable the identification of risks and define risk tolerances

- An FDA directive establishes general objectives for OES. According to the directive, OES's correspondence-related objectives are to (1) control and process all public correspondence directed to the Commissioner and (2) operate tracking systems to identify any bottleneck problems with executive correspondence.[9]

- OES has standard operating procedures that define more specific objectives for correspondence management, including expectations for responding to different categories of incoming correspondence. For example, the procedures state that correspondence from industry, advocacy groups, and organizations would generally be referred to the relevant FDA center or office, which would be expected to reply to the sender within 15 working days. In some cases, OES may allow more time for a center or office to reply, such as when a policy issue needs to be resolved before the response can be finalized.

[8]Food and Drug Administration, *Staff Manual Guide 2180.2 (Review of Complaints to FDA Sourced from Whistleblowers and Confidential Sources)* (May 3, 2024).

[9]Food and Drug Administration, *Staff Manual Guide 1111.3a* (Dec. 14, 2018).

Internal control standard: Management should design control activities to achieve objectives and respond to risks

- OES's standard operating procedures for correspondence analysts direct correspondence analysts to communicate with the responsible FDA centers or offices when those offices have not submitted responses within the expected number of days. OES officials told us that they also discuss correspondence with the Commissioner's Chief of Staff, when needed, to address any bottlenecks. Replies to correspondence are sometimes delayed as they are processed through an FDA center's director's office, the officials said. The OES Director or Deputy Director can decide to escalate cases to the Commissioner's Chief of Staff.

- OES staff rotate in-person presence at FDA's headquarters to receive and process physical mail. FDA's mail operating procedures, provided to us in February 2024, state that the mailroom staff take accountable mail—deliveries requiring a signature—to OES and obtain a signature from OES staff to document chain of custody.

- OES staff use FDA's AIMS to log incoming correspondence. In AIMS, staff must fill certain required fields to log a piece of correspondence, including the date the correspondence was received, the action to be taken in response, and the FDA office responsible for that action. According to OES staff, other FDA centers and offices use AIMS to monitor the status of responses to correspondence.

Internal control standard: Management should implement control activities through policies

- OES's standard operating procedures for correspondence analysts direct correspondence analysts to use AIMS to check for correspondence awaiting a response. OES officials described this as a manual process and stated that AIMS does not provide automated reminders to check on unanswered correspondence.

Internal control standard: Management should identify, analyze, and respond to significant changes that could impact the internal control system

- According to OES officials, OES prepares for personnel changes by training each correspondence analyst on working with each of FDA's product centers and major offices, so that analysts could cover each other's work assignments and be prepared for retirements or other staff departures. OES leadership also said they regularly discuss career plans and goals with employees, to help anticipate vacancies due to retirement or employee transitions.

Internal control standard: Management should internally communicate the necessary quality information to achieve the entity's objectives

- OES posts guidance for FDA staff on correspondence, including templates for responses to correspondence, on OES's site on FDA's intranet. The site is accessible to all FDA employees, according to OES staff.

- According to OES officials, OES management and staff meet regularly to share information about correspondence under review and discuss procedures for working with FDA centers and offices.

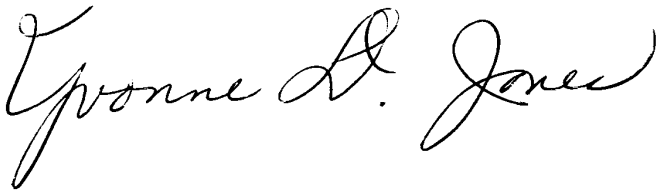
During our review, in April 2024, OES updated its standard operating procedures to document certain practices for processing correspondence. These updates reflect practices that OES staff described to us in interviews in February and March 2024. For example, the standard operating procedures now require that each correspondence analyst check AIMS weekly for correspondence awaiting a response.

The updated standard operating procedures should provide FDA management with increased assurance that OES is monitoring potential delays in responding to correspondence, as required by FDA policy. In addition, this documentation will aid OES in preparing for future staffing changes.

Agency Comments

We provided a draft of this report to the Department of Health and Human Services for review and comment. The agency provided technical comments, which we incorporated, as appropriate.

We are sending copies of this report to the relevant congressional committees and to the Secretary of Health and Human Services. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.
If you or your staff have any questions about this report, please contact me at (202) 512-6806 or JonesY@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are Sarah E. Veale (Assistant Director); Theodore Alexander (Analyst-in-Charge); Mark Canter; Ann Czapiewski; Rob Gebhart; Nkenge Gibson; Rebecca Hendrickson; Crystal Huggins; Peter Kramer; Steven Putansu; and Peter Verchinski.



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