SMG 3291.3a

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Records Management

Records Management Guidance for New and Departing Senior Officials

Effective Date: May 1, 2023

1. Purpose

This Staff Manual Guide (SMG) sets forth the records management requirements, policies, and responsibilities governing new and departing Senior Officials of the Food and Drug Administration (FDA), including orientation requirements when they assume a senior position; and exit process requirements for transfer or disposition (chain of custody) of their Federal records when leaving the Agency.

A separate SMG covers similar responsibilities and requirements for all other FDA non-senior official personnel (see SMG 3291.3, Records Management Guidance for New and Departing FDA Personnel).

2. Background

FDA Senior Officials, including political appointees, create, receive, and maintain Federal records as part of their official responsibilities. Official records of the FDA Commissioner, Deputy Commissioners, Associate Commissioners, Center Directors, Chief Counsel, Deputy Chief Counsels, Directors of significant policy and program offices, senior scientists, special consultants, and other senior advisory or principal management positions, often contain unique substantive information relating to policies, foods, drugs, medical devices, biologics and other regulated materials, as well as long-range issues of Agency-wide significance including administrative and operational information, that must be preserved as permanent records. All Senior Officials' records must remain in FDA custody, even after the associated official

departs the Agency. In addition to Federal records, Senior Officials may create and accumulate personal papers and nonrecord materials while in the workplace.

The National Archives and Records Administration (NARA), Department of Health and Human Services (HHS), and FDA have issued regulations and guidelines regarding the management of official records, personal papers, and nonrecord materials. This SMG supplements the overarching policy and requirements for managing FDA records that are outlined in SMG 3291.1, FDA Records Management Policy, and focuses on the records management requirements related specifically to the onboarding and departure processes for FDA Senior Officials.

3. Authorities and References

This SMG is derived from the Federal Records Act of 1950 (44 U.S. Code, Chapters 29, 31 and 33), as amended. It is aligned with the regulations issued by NARA in 36 CFR, Chapter XII, Subchapter B. Penalties for the unlawful removal or destruction of Federal records are described in Title 18 U.S.C. 641 and 2071.

Additional references relevant to this SMG include:

- NARA General Records Schedule (GRS) 6.1: Email Managed Under a Capstone Approach
- HHS-OCIO-PIM-2020-06-004, HHS Policy for Records Management, May 2020
- FDA SMG 3291.1, FDA Records Management Policy, September 2022
- NARA Federal Records Management website, Documenting Your Public Service
- FDA Office of Talent Solutions (OTS) Standard Operation Procedures - FDA OTS SOP 700-04 Processing Separations revised June 2019 (Final).pdf
- FDA SMG 3251.12, Information Security and Privacy Protection Policy, Attachment A, Appendix N: Use of Unauthorized External Information Systems to Conduct FDA Business
- NARA Bulletin 2015-02: Guidance on Managing Electronic Messages
- Inside.FDA - eDepart FDA Employee System

4. Definitions

This SMG addresses Federal records, nonrecord materials, and personal papers that are in the custody of FDA Senior Officials. The definitions of these key records

management terms can be found in the FDA Records Management Master Glossary.

5. Policy

This SMG applies to FDA personnel who serve in a designated FDA Senior Official position, whether they assume the position as a new hire or are appointed from within FDA to a new position. **Senior Officials**, for the purpose of this policy, are defined as the high-level positions identified as **Capstone Officials** for FDA's implementation of NARA's General Records Schedule (GRS) 6.1: Email Managed Under a Capstone Approach, as well as other high-ranking supervisory and scientific staff and special consultants designated by Centers and program offices as Non-Capstone Senior Officials. In GRS 6.1, NARA defines 10 categories of positions or roles within Federal agencies whose email warrant permanent retention. For FDA, Capstone officials include the following:

- FDA Commissioner,
- Deputy Commissioners,
- Associate Commissioners,
- Center Directors,
- Chief Counsel,
- Deputy Chief Counsels,
- Directors of significant policy and program offices, and
- Other senior advisory or principal management positions.

As noted above, the Capstone categories are used as a guideline to define the FDA Senior Official positions and may change over time. However, Capstone requirements of GRS 6.1, apply only to email at the current time, but this SMG applies to all records belonging to these officials, not just emails.

The complete list of FDA Capstone positions, by category, is approved by the FDA Records Officer (RO) and NARA on a reoccurring basis. Individuals serving in an "Acting" capacity in any of these positions longer than sixty (60) days are considered to be Senior Officials for the time period during which they temporarily serve in that role. A list of the individuals holding senior-level positions, including Capstone and Non-Capstone positions, is maintained by the FDA Office of Talent Solutions (OTS), Executive Resources Staff (ERS). ERS notifies the RO and Office of Enterprise Management Services (OEMS)/Division of Information Governance (DIG)/ Records Management Team (RMT) when changes are made to the list as Senior Officials are hired or depart from the Agency, or when individuals change positions.

The Federal Records Act, NARA regulations, and other statutes require all Federal agencies and employees to create records that document their activities, file records for safe storage and efficient retrieval, and dispose of records according to Records Control Schedules (RCS) approved by NARA. It is the responsibility of all FDA employees to document what they do and to protect Federal records in their

custody, in order to efficiently perform their work. Furthermore, for individuals in Senior Official positions within FDA, it is essential that they are aware of and implement good records management practices, because many of the records they create and receive document high-level Agency actions and decisions, and are likely to be permanent records that will eventually be transferred to the National Archives.

SMG 3291.1, "FDA Records Management Policy," describes and identifies the principles, standards, responsibilities, and requirements for managing FDA records, regardless of format, in compliance with applicable Federal laws, regulations, policies, and guidance. It provides the framework for records management program guidance and operating procedures for lifecycle records management, covering records creation or receipt, maintenance and use, and proper records disposition. This SMG outlines supplemental records management policies and procedures specific to new and departing FDA Senior Officials that are consistent with NARA's guidance for senior agency officials and political appointees, as described in Documenting Your Public Service.

A. Incoming FDA Senior Officials

The FDA RO, RMT, Center/Office Assistant Records Liaison Officer (ARLO), and/or designee as appropriate, will provide a records management awareness briefing to new individuals filling a Senior Official position within FDA. The records management briefing must be documented for accountability purposes, and should cover the following topics:

- The official's role(s) and responsibilities regarding records management, generally as a Federal employee, and those specific to FDA and the official's position.

- The importance of knowing that FDA records typically created, used, and maintained by Senior Officials, and the Center/Office or program for which they are responsible, are listed as permanent in the relevant FDA Records Control Schedules (RCS) and thus may not be destroyed.

- An overview of policies regarding ownership of official FDA records, maintaining personal papers and nonrecords as separate from official records.

- The importance of keeping personal business out of Agency administered systems and accounts.

- Guidance on FDA email policies and how the official's email is captured and maintained for permanent preservation as a Capstone account, including:

    - instruction on FDA's policy prohibiting the use of nonofficial electronic messaging accounts and personal devices for conducting official or

sensitive government business, per SMG 3251.12, Information Security and Privacy Protection Policy, Attachment A, Appendix N: Use of Unauthorized External Information Systems to Conduct FDA Business; and,

- if such nonofficial electronic accounts and/or personal devices are used in the case of exceptional circumstances, the official must copy or forward those messages to an official FDA account within 20 days, as required by the Federal Records Act (44 U.S.C. 2911 as amended).

B. Departing FDA Senior Officials

The FDA Office of Talent Solutions (OTS) provides comprehensive procedures for processing all FDA personnel separations. (See SOP 700-04, Processing Separations and eDepart, or successor SOP.) Guidance and procedures outlined in this SMG are specific to records management requirements.

When preparing to leave the FDA, departing Senior Officials will observe the following guidelines relative to FDA records in their control:

1. Departing Senior Officials must not destroy or remove Federal records from FDA, and they should take actions necessary so that their official records, whether in physical or electronic form, are available to their successor and/or can be retained by FDA for their full retention period as defined by applicable RCS. FDA records are the property of the Federal government, not the property of individual employees, and must not be removed from FDA without proper authority, as stated in SMG 3291.1, FDA Records Management Policy.

2. For records that are eligible for disposition in accordance with the approved RCS and not subject to any anticipated or actual litigation, Freedom of Information Act (FOIA), or other hold requirements, the ARLO in each Center/Office will assist with ensuring proper disposition procedures are carried out.

3. Generally, departing Senior Officials may take personal papers with them. Personal papers, whether in physical or electronic form, must be clearly designated as such and kept separate from official FDA records. Senior Officials should consult with the FDA RO, or other designated official to help determine whether files are personal or FDA records.

4. The FDA RO or designee should conduct an exit interview with a departing Capstone Senior Official as soon as possible prior to announced departure date, to address records management matters, as detailed in Section 7. The exit briefing should be documented for accountability purposes. The FDA RO or Center/Office Director or designee, may also choose to conduct an exit

interview with certain Non-Capstone Senior Officials, based on the nature of the official's duties and responsibilities.

5. Departing Senior Officials may not take copies of Federal records or nonrecord materials unless specifically authorized by the FDA RO. Section 7 outlines the procedures to follow to obtain clearance for removing copies of FDA records or nonrecords.

6. When possible, before leaving the Agency, departing Senior Officials must obtain clearance from their supervisor or designee, as well as the FDA RO or Center/Office ARLO for records-related items, following Agency procedures. The clearance process may involve a checklist or automated process, such as eDepart or successor systems, which provides a chain of custody that certifies they have returned all physical records in their custody and uploaded or transferred access to electronic records so they are available to their successor and preserved in accordance with applicable RCS.

   Senior Officials will work with administrative services within their Center/Office or with OTS as appropriate, to complete the exit process, and with the Executive Care Team in the Office of Digital Transformation (ODT) for related IT assistance.

7. Departing Senior Officials or designee should work with their Center/Office records management point of contact to dispose of **nonrecord materials** such as duplicate copies of records preserved only for convenience and reference materials that are no longer needed by their Center/Office for reference and/or other continuing use, and are not subject to any anticipated or actual litigation, FOIA, or other Federal hold requirements.

6. Responsibilities

A. Director, Office of Enterprise Management Services (OEMS).

- Approves, disseminates and implements Agency-wide policies for new and departing personnel, including Senior Officials, concerning records management responsibilities.

B. FDA Records Officer (FDA RO).

The FDA RO, with support from designated staff within RMT:

- Develops guidance on records management issues for new and departing FDA personnel, including Senior Officials, and evaluates compliance with Federal and HHS/FDA laws and guidelines.

- Provides awareness briefings to incoming Senior Officials on FDA records management policies and requirements and conducts exit interviews with Senior Officials to facilitate the transition and continued availability of FDA records.

- Coordinates with ODT Executive Care Team to capture and preserve electronic records of departing officials to enable continued access and preservation of FDA records for their full retention period.

C. **Assistant Records Liaison Officers (ARLOs).**

- Center/Office ARLOs provide records management training to new and departing Senior Officials in their Center/Office, as needed.

- Work with the Center/Office records staff, assist departing Senior Officials with return of Center/Office physical records to Center/Office document rooms, and transfer of access to electronic records, as applicable.

D. **Supervisors/Managers.**

- Advise departing Senior Officials to transfer official Agency records, including records maintained in a home office or on the employee's personal computing devices such as mobile phones and devices, hard drives, removable storage devices, or on other media.

- Provide staff with a chain of custody process to document transfer of records as part of the exit process. **Note**: For employees in Senior Official positions, this responsibility is typically performed jointly by the appropriate Center/Office Director or supervisor and the FDA RO or designee.

E. **Executive Resources Staff (ERS).**

- The ERS, within the Office of Talent Solutions (OO/OTS/ERS), maintains a list of current Senior Officials, both Capstone Officials and Non-Capstone Senior Officials. They also notify the FDA RO and Records Management Team when senior staff are onboarding and departing from FDA.

F. **Executive Care Team.**

- Provides direct assistance to FDA Senior Officials with information management tools and processes. Extracts and provides departing Senior Officials with copies of personal information contained in Agency information management systems and resources.

- Provides technical support needed to capture and preserve the departing Senior Official's FDA records, including emails and other electronic messaging formats, as directed by the FDA RO, and provides chain of custody in conveying those records to the appropriate program office recordkeeping system.

- Receives information management hardware from departing Senior Officials.

G. **FDA Senior Officials.**

- FDA Senior Officials, follow applicable Agency policies and procedures relating to records and information retention and disposition throughout their tenure at FDA and during the departure process.

Additional and more comprehensive RM responsibilities are identified in FDA SMG 3291.1, "FDA Records Management Policy," including overall responsibilities for the FDA RO and responsibilities for all FDA personnel.

7. Procedures Specific To Departing Senior Officials

Departing FDA Senior Officials are reminded of their legal obligation to manage and properly transfer government information and records prior to their departure from the Agency.

Before leaving the FDA, Senior Officials must take reasonable steps to facilitate processing Federal records in their control so that they may be properly managed and preserved by the Agency until their authorized disposition. In order to properly complete the records component of the eDepart process, Senior Officials should contact the FDA RO and their Center/Office ARLO or designee and assist with identifying their records so they can be transferred, reassigned, or archived as needed. Records from Senior Officials may be appropriately identified and captured from multiple sources, including, but not limited to:

- email, personal drives, essential records holdings, social media, or electronic messaging (including chats and text messaging) accounts (see note);

- internal and external advisory boards, committees, or councils in which the official participated; and

- reports to Congress and/or the President, speeches, testimonies, or major correspondence.

NOTE: Content from FDA social media accounts that are assigned to individual senior-level officials, such as the FDA Commissioner, Principal Deputy Commissioner, or other Capstone officials, must be preserved as permanent records. See Records

Management Guidance for FDA Social Media Content (sharepoint.com) for more details on social media records.

Uncirculated personal papers belong to Senior Officials and may be removed without review, provided they are not comingled with work-related documents. There may be situations in which personal and official files have been intermingled. Those files must be reviewed and the removal of personal materials approved by the FDA RO or designee, prior to the Senior Official's departure and following records management requirements. In cases where information about personal matters and FDA business appear in the same document, the document should be copied, the personal information should be deleted or redacted, and the copy treated as the official record. Non-public FDA information must be redacted from the personal copy, if being retained by the official.

If there is other information a Senior Official would like to remove from the FDA, they should contact the FDA RO. In general, senior officials should not have the expectation of taking copies of records or notes on work related documents with them because they are likely to contain non-public FDA information. The FDA RO's decision to approve the removal of any information requested must be subject to the following conditions:

- Removal would not adversely impact the official records of the Agency.
- Removal would be at no cost to the Agency.
- The materials do not contain classified national security information.
- The materials do not contain personally identifiable information (PII), proprietary, or sensitive information.
- Disclosure of the information to be removed is not otherwise prohibited by law.

8. Technical Assistance

Departing Senior Officials should contact the FDA RO or designee for questions regarding FDA records. Any violation of the statutory and regulatory limitations on the removal of documentary materials by FDA personnel who are separating from the Agency should be forwarded to the Office of Ethics and Integrity (OC/OO/OEI), the Director, Office of Enterprise Management Services (OC/OO/OEMS), the FDA RO, and the Center/Office ARLO, as applicable.

9. Effective Date

This effective date of this guide is May 1, 2023. It is an initial issuance.

10. Document History - SMG 3291.3a, Records Management Guidance for New and Departing Senior Officials

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
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