	FOR NARA USE ONLY
Number	GRS. 6.1-0088-2017-0001
Received Date	Apr 21, 2017
Total Accounts	49

Agencies are reminded that NARA reserves the right to review agency email practices and records. Pursuant to 36 CFR 1239.20, NARA may undertake an inspection involving high risk to significant records. Problems may be identified through a risk assessment or through other means, such as reports in the media, Congressional inquiries, allegations of unauthorized destruction, reports issued by the GAO or an agency's Inspector General, or observations by NARA staff members.

VERIFICATION FOR IMPLEMENTING GRS 6.1: EMAIL MANAGED UNDER A CAPSTONE APPROACH

SECTION A: Agency and Scope Information

This section captures general information about the agency and the scope of Capstone implementation. This includes: 1) name of the agency to which this form applies; 2) applicable record group number; 3) selection of which GRS 6.1 items the agency is proposing to use; and 4) information on implementation scope, such as whether agency-wide or limited to a specific component/office, as well as information on legacy email.

NOTE: One form is required for each unique implementation plan (for example, if implementation is limited to two program offices, but each program office differs in their implementation, one form for each is required) and/or per record group (RG) included (for example, a department implementing Capstone on behalf of their components which have separate record group numbers would need to submit one form per component/record group). This ensures that all positions are appropriately identified and documented. As a general rule, each record group number will require a separate form.

Name of Agency to Which this Form Applies:	U.S. Food and Drug Administration (FDA)				
Record Group Number:	0088				
** Please spell out	t full agency name. Please do not use acronyms.				
Is this form supe	s this form superseding a previous submission? YES NO				
If yes, provide p	previous tracking number assigned by NARA:				
, ,,	,, _F				
GRS 6.1 item(s) proposed for use:					
Implementation	Implementation scope for this submission: 🛛 Agency-Wide 🔲 Component/Office (explain in additional scope comments)				

Additional Scope Comments. If an agency did not check "all" under the "GRS 6.1 item(s) proposed for use" section, please summarize how other email is to be managed. If applicable, please include in this section all other RGs for which your agency is submitting a separate form (for example, "The department will also be submitting forms for the following additional components: [list of components, with their record group number]."
Not applicable.
** Note: Box will expand to accommodate text.
Cutoff Instructions. Agencies using item 010 must also include the cutoff instructions to be used for implementation (for example, "cutoff of email will be annual" or "cutoff of email will be by employee tenure").
Cutoff will be by employee tenure in a Capstone role.
** Note: Box will expand to accommodate text.
Transfer Instructions. Agencies using item 010 must also include the transfer instructions to be used for implementation (for example, "transfer when 15 years old" or "transfer when 20 years old"). Transfer time must be between 15 and 25 years when using GRS 6.1, item 010.
Transfer 15 years after cutoff.
** Note: Box will expand to accommodate text.
Legacy Email Scope. Agencies using this GRS are expected to apply the items being used to all legacy (existing) email. Please provide any general information on legacy email below (for example, "no legacy email exists for this agency, as traditional records management with a print-and-file policy was enforced prior to Capstone adoption" or "agency will be including legacy email for all items being used, dating back to approximately 2010.")
Where available, legacy emails dating back to 2010 will be included after being culled via GRS 6.1-proposed methods.
** Note: Box will expand to accommodate text.
Capstone Officials and Classified Accounts. Do any of the Capstone officials proposed on this list have email accounts on security classified networks or systems? NOTE: This information will be used by NARA ☐ YES ☐ NO for transfer planning purposes.
URL to Agency Organization Chart (If not available online, please attach with your submission. NARA reserves the right to request additional information to facilitate review):
Please see attached organization charts.
** Note: Box will expand to accommodate text.
Contact Information for Agency Records Officer (Name, Email, and Phone):
Tiffany Branch: Tiffany.Branch@fda.hhs.gov; (office) 240-402-3156
** Note: Box will expand to accommodate text.
Whom should NARA contact if there are any questions about this form, or the information contained within? (Name, Email, and Phone). NOTE: only complete if different from above.

Tom Koval: Thomas.Koval@fda.hhs.gov; (office) 240-402-3404

^{**} Note: Box will expand to accommodate text.

SECTION B: List of Capstone Accounts (GRS 6.1, item 010)

This section captures a listing of all positions or roles that fit into the definitions provided in item 010 of GRS 6.1. This section is broken down to correspond to the ten categories provided under item 010.

The number of accounts is an estimate of the number of accounts affiliated with an entry. For example, the head of the agency may be one Executive Director who utilizes two (2) different accounts to conduct business. In this case the entry would be "Executive Director" and the number of accounts would be "2."

Some agencies may not have any positions for certain categories. Please explain why under each applicable category. (For example, "We do not have any regional administrators" or "These positions are included under another submission" or "all the positions in this category are already covered in other categories.") Please refer to GRS 6.1, the corresponding FAQ #6, and the definitions provided within each category below for additional information on which positions must be included in a Capstone approach.

This section is required even in instances where only the temporary items (011 and/or 012) are being used, in which case it acts as an exception list.

NOTE: the list should be of positions or roles (for example, "Secretary"), not specific individual names or email addresses (for example, "John Smith" or "John.Smith@agency.gov"). Agencies may summarize or condense specific levels of management, rather than repeat positions. For example, an agency may input one entry for "All Under-Secretaries" with a position total that represents the number of said positions, rather than listing out each specific Under-Secretary.

Category 1) The head of the agency, such as Secretary, Commissioner, Administrator, Chairman or equivalent. The very top executive of the agency. For cabinet level agencies, this is typically a Secretary. For independent agencies, and components within cabinet level agencies, this may be a Commissioner, Administrator, Director, or a specialized title (such as "Archivist of the United States"). For other agencies, including Commissions and Boards, this may be a Chairman, Executive Director, a group of Commissioners, Council Members, Board Members, or the equivalent. Most agencies will have one position for this category (although the one position may have multiple email accounts); some agencies, such as Commissions and Boards, may have multiple positions in the category. *If no positions are identified, please briefly explain why (for example, "Not applicable; no positions in this category exist.")

POSITION TITLE / ROLE		# of Accounts	
Add Row	Remove Last Row	Commissioner of Food and Drugs	2
(total number of accounts for this category; this number will auto-populate)		2	

Category 2) Principal assistants to the head of the agency (second tier of management), such as Under Secretaries, Assistant Secretaries, Assistant Commissioners, and/or their equivalents; this includes officers of the Armed Forces serving in comparable position(s). Generally the second-tier of management within an agency, this may include Under Secretaries, Assistant Secretaries, Assistant Commissioners, Vice Chairmen, etc. Some agencies may use other terminology, such as "Associate." The number of positions at this level will vary greatly agency to agency. Some may only have one, such as an Assistant Commissioner, while others may have multiple, such as numerous Assistant Secretaries each with oversight of a specific program, bureau, or line of business within the agency. *If no positions are identified, please briefly explain why (for example, "Not applicable; no positions in this category exist.")

		# of Accounts	
Add Row	Remove Last Row	Associate Commissioner, Office of External Affairs	1
Add Row	Remove Last Row	Associate Commissioner, Office of Women's Health	1

(total number of accounts for this category; this number will auto-populate)	2
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Category 3) Deputies of all positions in categories 1 and 2, and/or their equivalent(s). Most of the first- and second-tier executives covered in the first two categories have corresponding deputy position(s) that assist in the daily operations of the agency. This includes Deputy Secretaries, Deputy Commissioners, Deputy Assistant Commissioners, etc. The number of deputy positions will also vary greatly from agency to agency. *If no positions are identified, please briefly explain why (for example, "Not applicable, no positions in this category exist.")

		# of Accounts	
Add Row	Remove Last Row	Deputy Commissioner, Office of Foods and Veterinary Medicine	1
Add Row	Remove Last Row	Deputy Commissioner, Office of Global Regulatory Operations and Policy	1
Add Row	Remove Last Row	Deputy Commissioner, Office of Policy, Planning, Legislation, and Analysis	1
Add Row	Remove Last Row	Deputy Commissioner, Office of Operations & Chief Operating Officer	1
Add Row	Remove Last Row	Deputy Commissioner, Office of Medical Products and Tobacco	1
	(to	5	

Category 4) Staff assistants to all positions in categories 1 and 2, such as special assistants, confidential assistants, military assistants, and/or aides. For those senior officials in categories 1 and 2, important work is often carried out by special assistants, confidential assistants, military assistants, aides, executive assistants, etc. They may send email on behalf of senior officials and/or their email account contains email closely related to the responsibilities and actions of the senior officials they support. For example, a "special assistant" to the Secretary of Defense, or a "Counselor" to Secretary of Health and Human Services would fall into this category. *If no positions are identified, please briefly explain why (for example, "Not applicable, no positions in this category exist.")

	POSITION TITLE / ROLE		# of Accounts
Add Row			1
	(total number of accounts for this category; this number will auto-populate)		1

Category 5) Principal management positions, such as Chief Operating Officer, Chief Information Officer, and Chief Financial Officer, and/or their equivalent(s). These positions tend to be those executives who have operational and management responsibilities within an agency, including Chief Operating Officer, Chief Information Officer, Chief Knowledge Officer, Chief Technology Officer, and Chief Financial Officer. These positions are often required by statute or Executive Order, such as, for example, the Chief Financial Officer Act and the Chief Technology Officer Act. For some agencies, these positions may already be covered by other categories. *If no positions are identified, please briefly explain why (for example, "Not applicable; no positions in this category exist.")

	POSITION TITLE / ROLE		# of Accounts
Add Row	Remove Last Row	Chief Scientist, Office of the Chief Scientist	1

Add Row	Remove Last Row	Chief Financial Officer & Director, Office of Finance, Budget, and Acquisitions, Office of Operations	1
Add Row	Chief Information Officer & Director, Office of Information Management, Office of Information Management and Technology, Office of Operations		1
	(total number of accounts for this category; this number will auto-populate)		3

Category 6) Directors of significant program offices, and/or their equivalent(s). Those Directors (or equivalents, such as Executive Directors, Managers, Directorates, or Chiefs) that oversee and manage major program offices, bureaus, or lines of business that support the agency mission. For example, many agencies will have a Director that oversees Congressional and Legislative affairs, or a Director that oversees one specific mission-related program office. For some agencies, these positions may already be covered by other categories. *If no positions are identified, please briefly explain why (for example, "Not applicable; no positions in this category exist.")

POSITION TITLE / ROLE			# of Accounts
Add Row	Remove Last Row	Associate Commissioner, Office of Public Health Strategy and Analysis, Office of Policy, Planning, Legislation, and Analysis	1
Add Row	Remove Last Row	Associate Commissioner, Office of Special Medical Programs, Office of Medical Products and Tobacco	1
Add Row	Remove Last Row	Director, Office of the Executive Secretariat	1
Add Row	Remove Last Row	Director, Office of Safety, Security, and Crisis Management, Office of Operations	1
Add Row	Remove Last Row	Associate Commissioner, Office of Policy, Office of Policy, Planning, Legislation, and Analysis	1
Add Row	Remove Last Row	Associate Commissioner, Office of Planning, Office of Policy, Planning, Legislation, and Analysis	1
Add Row	Remove Last Row	Director, Office of Legislation, Office of Policy, Planning, Legislation, and Analysis	1
Add Row	Remove Last Row	Associate Commissioner, Office of International Programs, Office of Global Regulatory Operations and Policy	1
Add Row	Remove Last Row	Associate Commissioner, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy	1
Add Row	Remove Last Row	Director, Center for Drug Evaluation and Research	1
Add Row	Remove Last Row	Director, Office of Resource Planning and Strategic Management, Office of Foods and Veterinary Medicine	1
Add Row	Remove Last Row	Director, Office of Coordinated Outbreak Response and Evaluation Network, Office of Foods and Veterinary Medicine	1
Add Row	Remove Last Row	Director, Office of Minority Health	1
Add Row	Remove Last Row	Director, Center for Devices and Radiological Health	1
Add Row	Remove Last Row	Director, Center for Food Safety and Applied Nutrition	1
Add Row	Remove Last Row	Director, Center for Veterinary Medicine	1
Add Row	Remove Last Row	Director, National Center for Toxicological Research	1
Add Row	Remove Last Row	Director, Center for Biologics Evaluation and Research	1

Add Remove Last Row Director, Center for Tobacco Products		Director, Center for Tobacco Products	1
	(total number of accounts for this category; this number will auto-populate)		19

Category 7) Principal regional officials, such as Regional Administrators, and/or their equivalent(s). Those agencies with a regional structure must include the accounts of principal regional officials. For most agencies with a regional presence this will be limited to Regional Administrators, or those officials who are responsible for the management and operations of specific regional areas (e.g., an agency that has 10 regions to carry out mission-critical activities would include those 10 Regional Administrators). It does not pertain to the heads of individual offices within regions, such as, but not limited to, customerservice centers, processing centers, or administrative offices that conduct routine activities (e.g., passport offices, or Social Security claims processing offices). *If no positions are identified, please briefly explain why (for example, "Not applicable; no positions in this category exist.")

		POSITION TITLE / ROLE	# of Accounts
Add Row	Remove Last Row	Regional Food and Drug Director, Central Region	1
Add Row	Remove Last Row	Regional Food and Drug Director, Northeast Region	1
Add Row	Remove Last Row	Regional Food and Drug Director, Pacific Region	1
Add Row	Remove Last Row	Regional Food and Drug Director, Southeast Region	1
Add Row	Remove Last Row	Regional Food and Drug Director, Southwest Region	1
(total number of accounts for this category; this number will auto-populate) 5		5	

Category 8) Roles or positions that routinely and directly advise the above positions, including special advisers, General Counsels, Chiefs of Staff, Inspectors General, etc. Many management positions routinely provide advice and oversight to the agency in the course of daily business, and are involved in mission related policy formulation, implementation, and/or interpretation. This may include general program oversight, legal protection and oversight, and daily operations and management. For most agencies this will include General Counsels, Chiefs of Staff, Inspectors General and special advisers (such as "Policy Advisors") within the top tiers of the agency. This does not include those that advise on purely administrative issues. For example, a Chief of Staff within a lower tier of the agency would not be included in this category. *If no positions are identified, please briefly explain why (for example, "Not applicable; no positions in this category exist.")

		POSITION TITLE / ROLE	# of Accounts
Add Row	Remove Last Row	Chief of Staff, Office of the Commissioner	1
Add Row	Remove Last Row	Chief Counsel, Office of the Chief Counsel	1
	(to	2	

explain why (for example, "Not applicable; no positions in this category exist.") categories 1 through 8, and no other PAS positions will need to be identified. *If no positions are identified, please briefly (PAS) but not represented in any of the other categories. For most agencies the PAS positions will already be captured in positions). This category is a catch all for any position that was filled by Presidential Appointment with Senate Confirmation Category 9) Roles and positions not represented above and filled by Presidential Appointment with Senate Confirmation (PAS

(total number of accounts for this category; this number will auto-populate)	Add Remove Not applicable; no positions in this category exist. 0	# of Account # of Account
		of Accounts

other nine (9) categories. *If no positions are identified, briefly explain why (for example, "Not applicable; no positions in this significance. This category is for those roles and positions that are appropriate for permanent retention, but not captured in the that predominantly create permanent records related to mission critical functions or policy decisions and/or are of historical or policy decisions and/or are of historical significance. These represent roles, positions, and/or programs within the agency category exist.") Category 10) Additional roles and positions that predominately create permanent records related to mission critical functions

10	(total number of accounts for this category; this number will auto-populate)	(tc	
1	Principal Deputy Chief Counsel	Remove Last Row	Add Row
6	Last Row Deputy Chief Counsel	Remove Last Row	Add Row
1	Counselor to Deputy Commissioner for Policy, Planning, Legislation, and Analysis	Remove Last Row	Add Row
1	Remove Senior Science Advisor, Office of Foods and Veterinary Medicine	Remove Last Row	Add Row
1	Remove Deputy Chief Operating Officer	Remove Last Row	Add Row
# of Accounts	POSITION TITLE / ROLE		

SECTION C: Agency Approvals

NOTE: Approvals must be completed digitally.

the National Archives and Records Administration. The information provided on this form will be made publicly available, unless the agency provides, in its email submission, NARA with a proper citation requiring the protection of this information By checking these boxes, you are confirming that this form has been reviewed and approved by the appropriate agency officials, and is ready for review by

Jan 4, 2017	ved	Senior Agency Official, Records Management Colleen Barros, Acting Assistant Secretary for Administration
Dec 6, 2016		Agency Records Officer Tiffany Branch, FDA Records Officer
DATE	APPROVAL	TITLE and PRINTED NAME

scanned to PDF forms will not be accepted. You may also submit the form automatically by pressing here: Submit this form as an attachment to an email to GRS_Team@nara.gov for processing and approval. Hard-copy or printed and

Submit by Email

If denied, reason: Chief Records Officer for the U.S. TITLE and PRINTED NAME Laurence Brewer \boxtimes Approved STATUS Denied Nov 7, 2017 DATE

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