**SMG 1005.1**

# FDA Staff Manual Guides, Volume I - Organizations and Functions

## Organizational Changes - Policy

## Policy and Procedures Regarding Organizational Changes

Effective Date: March 25, 2022



### 1. Purpose.

This Guide provides policy and procedures governing the development, evaluation, coordination, review, and approval of all organizational changes within the Food and Drug Administration (FDA).

### 2. References*.

This Guide supplements policy and procedures set forth in the following directives:

A. General Administrative Manual Chapter HHS: 8-60, “Securing Approval of Organizational Changes”;

B. General Administrative Manual Chapter HHS: 8-65, “Organizational Nomenclature”;

C. General Administrative Manual Chapter HHS: 8-69, “Standard Administrative Code”;

D. Organization and Functions Staff Manual Guides FDA 1010.1, “Control and Use of Standard Administrative Codes” https://www.fda.gov/media/81831/download;

E. Delegations of Authority Staff Manual Guide FDA 1415.5, "Authority to Approve Organization Structures and Functional Statements" https://www.fda.gov/media/82007/download; and

F. FDA Organization(s) and Functions are available on the intranet site located at

http://inside.fda.gov:9003/PolicyProcedures/StaffManualGuide/VolumeIOrganizationsandFunctions/default.htm.
New link: https://fda.sharepoint.com/sites/OC-Intranet-OC-OO-OEMS-DIG-RMT-Staff- Manual-Guides/SitePages/Organizations-and-Functions,-Volume-I-1000-1300.aspx

*See your Reorganization Point of Contact for additional information.

**3. Definitions.**

A. **Organizational Component**. Any part of the FDA organization that is separately established as an organizational entity by law, regulation, the Secretary, or an official who has been delegated authority and who has formally assigned functions, an approved Standard Administrative Code (SAC), and title. Informal organizations, such as teams, task forces, and working groups are not considered to be organizational components.

1. **Office**. The apex or top echelon level organizational component responsible for the leadership, oversight and management, guidance, and support of core program activities and line sub-structure organizational components.

2. **Division**. A line type organizational component that directly reports to an Office level organization. Responsible for directing, oversight and supervision, and execution of core functional activities.

3. **Branch**. A line type organizational component that directly reports to a Division level organization. Responsible for performing line or core functional activities.

4. **Staff**. A support type organizational component that directly reports to an Office or a Division level organization. Responsible for non-core or designated secondary functional activities such as administrative functions (Acquisitions, Budget, Facilities, Human Resources, and Information Technology or systems) or management functions (Analysis, Evaluation and Reporting, Communications, legal and legislation, and Planning and Policy).
5. **Team(s), Task Force, or Working Group(s) (Informal Organizations)**. An informal component, generally small in size, assembled at leadership's discretion, to address and complete a very specific assignment or project.

B. **Organizational Change**. A change to any part of an official organization that includes the establishment, abolishment, transfer, realignment, or consolidation of an organizational component, including name change, change in reporting

relationships, and/or addition, modification, abolishment, or transfer of function(s).

C. **Functional Statement**. A formal description of the mission assigned to an organizational component, all inherent responsibilities, and the activities conducted within the component to accomplish that mission. It describes the purpose, scope, and nature of the work proposed within each organization. Functional statements are required for Office and Division organizational units. Organizational subcomponents, including Staff, Branch, Laboratory, or Section organizations, are included in their parent organization's functional statement.

D. **Standard Administrative Code (SAC)**. A unique identifier assigned to each organization. The SAC is the common organizational identifier for all organizations in the Department of Health and Human Services (HHS). The HHS General Administrative Manual (GAM) 8-69 specifies the code structure.

E. **Leadership Charts**. Organizational charts reflecting FDA's top-level organizational structure. These charts depict the reporting hierarchy, organization, and leadership position titles, leader's name, and assigned SAC codes. These charts are required to be updated and submitted for publication once a reorganization has been approved and the implementation process has been initiated.

F. **Effective Date**. The reorganization will be legally in effect once approved by the appropriate authority and the 30-day Congressional Notification period has completed, unless otherwise directed by the Department.

G. **Implementation Date**. Date determined by FDA to implement an approved and effective reorganization. It is the policy of the FDA that no restructuring actions be implemented until the reorganization is approved by an appropriate official with the delegated authority, the 30-day Congressional notification period has lapsed, and, if applicable, a bargaining agreement is in place.

H. **Notification of Organizational Approval and/or Request Standard Administrative Code (SAC) Revision Form (NOA Form)**. HHS Form 509A is submitted to Department of Health and Human Services (HHS) to reflect the updated SACs for a reorganization.

I. **Notification of Organizational Approval Package (NOA Package)**. The official document set that adjusts central organizational records and informs the appropriate officials of the organizational change. This set includes the legal documents of record, including the NOA Form and updated Functional Statements.

J. **Echelon**. The hierarchical location (organizational level) of an organizational component, regardless of its title, that is based on the reporting relationships specified below. (See Attachment A.)

1. **First Echelon**. The level of an organizational component whose head official reports directly to the Secretary.

2. **Second Echelon**. The level of an organizational component whose head official reports directly to the Commissioner.

3. **Third Echelon**. The level of an organizational component whose head official reports directly to a second echelon official head.

4. **Subsequent Echelons**. For each level of an organizational component, official heads report directly to the previous level official head, e.g., a fourth echelon official head reports to a third echelon official head.

## 4. Organizational Planning Policy.

A. **Overall Policy**. The FDA will utilize structures that provide efficient and effective means for accomplishing assigned functions within the realm of available resources. Organizations should be lean and agile in their operations and may be flat without any subcomponents. If an organization intends to create subcomponents, they must meet the following criteria.

B. **Criteria**. Organizational changes should enhance productivity and effectiveness in accomplishing current and long-range goals of the organizational component. The following must be factored into the consideration of proposed organizational changes: budget implications (such as appropriations; reprogramming; and/or limitations); position management; restrictions on hiring and promotions; and aligned with FDA, HHS, and/or government-wide strategic plans, priorities, and initiatives.

It is a leadership and management responsibility to structure organizations, so that supervisory layering is avoided. This can be accomplished by increasing supervisory spans of control, using informal “teams” rather than formal organizations, reducing layers of oversight, and empowering lower organizational echelons.

Organizational structures should be as simple as possible, while maintaining responsive customer service and high productivity. As a general rule, formal organizations should not be created below the fifth echelon. The guiding principles related to organizational components are:

1. **Component Functions**. The proposed functions of the new organization must be clearly distinct and the type, difficulty, and volume of work to be

assigned to the new organization must be such that redistribution of tasks between existing organizations is not feasible. In addition, the consolidation of organizational components should be fully considered when supervisory positions are vacated.

2. **Resources**. The organization's budget must be adequate to meet its obligations and avoid violating the Anti-Deficiency Act.

3. **Component Size**. As a rule, there are no fewer than 10 full time equivalents (FTE) for official components at any level of the organization. Generally, Offices and Divisions contain at least 20 FTE positions (including funded vacancies), and Branches and Staffs contain at least 10 FTE positions (including funded vacancies). Contractors are excluded. Super Office organizations must contain at least 120 FTEs. Super Office organizations typically exceed five echelons, their proposal must be approved by HHS.

4. **Organizational Layers**. Organizational layers typically include Offices, Divisions, and Branches. As a general rule, organizations should be as flat and resource- efficient (lean) as possible. Administrative and management organizations should adhere to HHS's suggested lean and simple or flat organizational structure. HHS defines "lean" as minimum resources needed to perform functions. If sub-organizational layering is necessary, there must be at least two components (i.e. two branches or staffs within a Division). Staffs are considered support organizations. There may be as few as one staff or multiple staffs within an Office or Division.

5. **Supervisory Layering**. Supervisory layering typically includes positions of supervision within organizational components and their respective reporting relationships. Layering causes too many supervisory levels in the chain of command and is not recommended. Ensure supervisory ratios are in compliance with HHS and Operating Division/Staff Division (OPDIV/STAFFDIV) staffing plans and goals. Supervisory ratio goal is 1:10.

6. **Management Factors**. Other considerations include: maintaining a reasonable span of control; centralizing or decentralizing functions; maintaining clear and appropriate lines of authority and responsibilities between organizations; providing for optimal resource utilization; keeping line and staff functions in separate components; and ensuring that the rights of employees are not violated.

7. **Employee Utilization**. Organize components and structure work to fully utilize and leverage existing staff talent. Positions should span several grade levels to provide for internal promotions and job recruitment at the entry level.

8. **Delegations of Authority**. Review and conduct an evaluation of all Delegations of Authority (Administrative and Regulatory) for possible impacts

to the operations of the organization. Seek assistance and guidance from the appropriate Center/HQ Office/Office of Regulatory Affairs (ORA) Component Delegation Control Officer.

9. **Policy or Public Interest Implications**. Identify any organizational changes that have statutory mandates, policy, or public interest implications. These changes may involve HHS interorganizational relationships on health policy; significant changes in programmatic interrelationships with local, State, and/or other Federal government organizations; members of Congress, the Office of Management and Budget (OMB), press media, advocacy groups, institutions, labor unions, etc.; or present the potential for inquiry or complaint addressed to the Secretary.

10. **Office of Inspector General (OIG) Audits and Government Accountability Office (GAO) Study Implications**. Proposals for organizational change will need to state if any OIG or GAO audits or studies were conducted within the last five years involving the affected organization's components or programs. Address how the proposal potentially affects the OIG/GAO recommendations and how compliance will be met.

11. **Moratoriums**. The FDA requires a duration period of two fiscal years, starting from the FDA submission date of an organizational component's last approved reorganization of that component, before another reorganization proposal may be submitted for consideration. Exceptions to this moratorium must be approved by the Executive Committee. For example, a division that submitted to FDA a reorganization package in FY 2019 will not be eligible, without alignment from the EC, to re-submit a new reorganization proposal until FY 2021. HHS, OMB, and/or Congress may place additional oratoriums, such as during an election year.

12. **FDA and HHS Review and Clearance**. The reorganization program is on a fiscal year cycle. An annual kick-off to present new requirements, if any, timeline of the process cycle, and announcement of the data call will be conducted in the first quarter of every new fiscal year. Proposals will be presented by the Center/Office(s) Executive Officer, and the affected organization's subject matter expert(s) to FDA Headquarters clearing organizations. All proposals will then be consolidated and submitted to FDA Senior Leadership for review, selection, and prioritization for submission to HHS.

C. **Preparing Reorganization Packages**. The Office of Operations has coordination and oversight responsibility for reorganizations within the FDA. Contact FDA's Reorganization Coordinator(s) for the Standard Operating Procedures (SOP) for preparing reorganization packages. The SOP outlines roles, responsibilities, and required documents for review, clearance and approval, and includes samples and templates.

## 5. Organizational and Titling Nomenclature.

An organizational component's title should be descriptive of the component's basic functions. The FDA's organization will normally conform to the following nomenclature:

A. **Organizational Hierarchies**:

| Echelon | Center Example | Office Example |
|---|---|---|
| First | Center | Office |
| Second | Office | Division or Staff |
| Third | Division or Staff | Branch or Staff |
| Fourth | Branch or Staff | |

Laboratories, Resident Posts, and Centers of Excellence are anomalies. These types of organizations may be found at the second through fourth echelon levels.

B. **Special Instructions Concerning Use of the Designation "Staff"**. The designation "Staff" identifies support organizational components not suitable for designation as an Office or Division, and with a recommended minimum of 10 FTE. A staff may only occur at the Center, Office, and Division organizational levels.

C. **Title Nomenclature**. The title nomenclate for Centers, Offices, and Divisions must begin with the organizational component level nomenclature title first, followed by words that reflect its functions and program activities, such as the Center for Drug Evaluation and Research, Office of Compliance, and Division of Enforcement or for "Staff" or "Branch" organizational component title nomenclature, the preceding words that reflect the functions or program activities, such as the Regulations Policy Management Staff or the Vendor Payments Branch. Organizations are prohibited from using position titles as part of the organizational title, i.e., Consumer Safety Officer Staff. Center and ORA organizations are generally prohibited from using organization titles that are reserved for FDA HQ component organizations (ex: Executive Secretariat, Office of Policy, Office of Operations, etc.).

Organizations must try to avoid titling substructure components with the same title. If necessary, Office and Division level organizations with the same title must be differentiated by using Roman numerals (e.g. Division of Drug Review I and Division of Drug Review II). Lower level echelon organizations, such as Staff and Branch organizations, may use Arabic numbers at the end of the title to differentiate organizations with the same title (e.g. Contracts Branch 1 and Contracts Branch 2).

D. **Exceptions**. Exceptions to the recommended nomenclature include, but are not limited to:

1. Organizations prescribed by statute or legislatively mandated

2. Libraries, Laboratories, etc., i.e., FDA Bioscience Library or Gulf Coast Seafood Laboratory

An Office/Center may request an exception or special waiver by submitting a justification memorandum to the Commissioner. Exceptions specifically pertaining to the moratorium, can be made under certain circumstances, such as in response to: new legislative mandates; a public health emergency; or unanticipated new workload or program demands; and should also be presented to the Executive Committee. The justification must include the purpose, benefit, and the negative impact if the exception is not granted. Note: Exemptions are specific to this guidance requirements. Human resources, budget, and financial management requirements must be addressed via the policy and procedures of the FDA's Office of Human Capital Management, Office of Talent Solutions, Office of Budget, and Office of Financial Management as well as HHS, OMB, Office of Personnel Management, and Congress.

**6. Approval Authority.**

A. **Secretarial Approval**. The Secretary retains the authority to approve all organizational changes that involve:

1. More than one organizational component with an operational mission or function.

2. A statutorily-based or legislatively-mandated organization (Consult with the Office of Chief Counsel (OCC) for more information on applicability).

3. A significant reorganization which may affect the public. These may include the reorganization of multiple offices within the Commissioner's Office or the realignment of functions that have a direct impact on the public.

B. **FDA Commissioner Approval**. Subject to HHS clearance, the FDA Commissioner retains the authority to approve all 1st and 2nd echelon reorganizations, except those noted in 6.A. above. This authority may be further delegated as per SMG 1415.5.

**7. Congressional Notification, Official Publication, and Reorganization Effective Date.**

A. Beginning with the December 11, 2015, enacted Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriation, Congress

requires formal notification before a reorganization proposal is effective. The Congressional notification period is 30 days.

B. Once the Congressional notification period has been completed, the Federal Register Notice must be reviewed and approved by the Reorganization Program prior to publication.

C. FDA implementation of an approved reorganization following the Congressional and Union notification periods includes processing of the new SACs and employee realignment. See FDA's HR program for guidance on impacts to other HR actions.

## 8. Effective Date.

This guide was approved by the FDA Deputy Commissioner for Operations and Chief Operating Officer on March 16, 2022 and is effective on March 25, 2022.

## 9. Document History – SMG 1005.1, "Policy and Procedures Regarding Organizational Changes"

| Status (I,R,C) | Date Approved | Location of Change History | Contact | Approving Official |
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| Revision | 09/26/2007 | N/A | FDA Office of the Commissioner, Office of Management | John R. Dyer, Deputy Commissioner for Operations |
| Revision | 04/23/2010 | N/A | FDA Office of the Commissioner, Office of Management Programs | Russell J. Abbott, Deputy Commissioner for Administration |
| Revision | 09/25/2012 | N/A | FDA Office of Operations | Walter S. Harris, Chief Operating Officer |
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