STAFF MANUAL GUIDE 1005.1

FOOD AND DRUG ADMINISTRATION

ORGANIZATIONAL CHANGES - POLICY

POLICY REGARDING ORGANIZATIONAL CHANGES

I. 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).

II. 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 Delegations Staff Manual Guide FDA 1415.5, "Authority to Approve Organization Structure and Functional Statements"; and

E. Agency Organization(s) are available on the FDA Internet site located at http://inside.fda.gov:9003/PolicyProcedures/StaffManualGuide/VolumeIOrganizationsandFunctions/default.htm.

III. 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, has formally assigned functions and an approved Standard Administrative Code (SAC) and title. Informal organizations such as teams, task forces, and working groups are generally not considered to be organizational components.

B. **Organizational Change**. The term "organizational change" includes the establishment, abolishment, transfer, realignment or consolidation of an organizational component; 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.

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. **Notification of Organizational Approval**. The official document (FDA form 2755A) which adjusts central organizational records and informs the appropriate officials of the organizational change.

F. **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 reports directly to the Secretary.

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

3. **Third Echelon**. The level of an organizational component whose head reports directly to a direct report to the Commissioner.

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

IV. ORGANIZATIONAL CHANGE POLICY.

A. **Overall Policy**. The Agency will utilize structures that provide efficient and effective means for accomplishing assigned functions within the realm of available resources. Organizations must subdivide into two or more elements.

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; and restrictions on hiring and promotions.

It is a managerial 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/or; the type, difficulty, and volume of work to be assigned to the new organization are 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. **Component Size.** Offices and Divisions must contain at least 16 FTE positions (including funded vacancies), and Branches and Staffs must contain at least 8* FTE positions (including funded vacancies). Contractors are excluded.

3. **Organizational Layering**. Organizational layering typically includes Offices, Divisions and Branches. If sub-organizational layering is necessary there must be at least two components.

4. **Supervisory Layering**. Supervisory layering typically includes positions of supervision within organizational components and their respective reporting relationships. Layering is too many supervisory levels in the chain of command.

5. **Management Factors**. Other considerations include maintaining a reasonable span of control, centralizing or decentralizing, maintaining appropriate lines of authority and responsibility, providing for optimal personnel utilization, keeping line and staff functions in separate components, and ensuring that the rights of employees are not violated.

6. **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.

7. **Policy or Public Interest Implications.** The Office of Budget (OB) and Office of Operations (OO) should be notified, within five (5) working days, about organizational changes that have statutory mandates, policy or public interest implications. These changes involve HHS interorganizational relationships on health policy; significant changes in programmatic interrelationships with local, State, and/or other Federal government organizations; members of Congress, OMB, the

press, advocacy groups, institutions, labor unions, etc.; or present the potential for inquiry or complaint addressed to the Secretary.

8. **Moratoriums.** A duration period of one year starting from the effective date of an organizational component's last approved reorganization must pass before another reorganization proposal may be submitted for approval.

*Based on the HHS guidelines for supervisor ratios.

C. **Preparing Reorganization Packages**. The Office of Operations has coordination and oversight responsibility for reorganizations within FDA. Standard Operating Procedures (SOP) for preparing reorganization packages may be found in Attachment B of this SMG. The SOP outlines roles and responsibilities and includes samples and templates.

V. ORGANIZATIONAL 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. **Line Organizations**:

Headquarters	Field
Directorates/Office	Directorate
Center/Office	Office of Regulatory Affairs
Office	Office/Regional Office
Division	District Office/Regional Laboratory
Branch/Staff	Branch/Staff
	Resident Post

B. **Special Instructions Concerning Use of the Designation "Staff."** The designation "staff" should be utilized to recognize organizational components not suitable for designation as an Office or Division and with a minimum of 8 positions. It may occur at various organizational levels.

C. **Special Instructions Concerning Use of the Designation "Team."** The designation "team" should be utilized to identify informal organizational components with fewer than 8 positions. A team allows more flexibility than a formal organization; it can be established or disbanded without preparing a formal reorganization proposal.

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

1. Organizations prescribed by statute or legislatively mandated; and

2. Area Offices, libraries, laboratories, etc.

3. Resident Posts may not have a function separate from the Investigations Branch.

4. An Office/Center may request an exception or special waiver by submitting a justification memorandum to the Commissioner through the Chief Operating Officer

(COO). The justification must include the purpose, benefit, and the negative impact if the exception is not granted.

VI. 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. Examples 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**. The FDA Commissioner retains the authority to approve all 1st and 2nd echelon reorganizations, except those noted in **VI.A.** above.

C. **Deputy Commissioner, Chief Scientist, Chief Operating Officer (COO) and Center Directors/Associate Commissioner for Regulatory Affairs (ACRA)**.

Deputy Commissioners, Chief Scientist, COO and Center Directors/ACRA are delegated authority to approve all third echelon and below reorganizations with prior review and concurrence by the Director, Office of Business Services/Management Analysis Staff with the exception of those noted in **VI.A.** above.

VII. REORGANIZATION EFFECTIVE DATE.

The reorganization effective date is the date the authorized approving official (i.e., the Secretary, Commissioner, or Center Director/ACRA as previously determined), by virtue of his/her signature, signs and dates the official request.

Note: Although the request for reorganization has been approved, no movement of employees or filling of positions in the new organization may occur until OHR has approved and keyed in the SAC(s) into the OHR personnel database. Once this process has occurred, OHR begins processing the movement of employees to new positions and to new administrative codes.

VIII. EFFECTIVE DATE. Approved by the Chief Operating Officer, effective on TBD.

IX. DOCUMENT HISTORY

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	SMG 1005.1, Policy and Procedures Regarding Organizational Changes	
			CONTACT	APPROVING OFFICIAL
Revision	09/26/2007	N/A	FDA Office of the Commissioner, Office of Management	John R. Dyer, Deputy Commissioner for Operations and Chief Operating Officer

Revision	04/23/2010		FDA Office of the Commissioner, Office of Management Programs	Russell J. Abbott, Deputy Commissioner for Administration
Revision	MM/DD/YYYY	N/A	FDA Office of Operations,	

Standard Operating Procedures For FDA Reorganizations

U.S. Department of Health and Human Services
Food and Drug Administration

March 6, 2013

OFFICE OF OPERATIONS
OFFICE OF HUMAN RESOURCES
MANAGEMENT ANALYSIS SERVICES STAFF

Table of Contents

Standard Operating Procedure For Reorganizations

Purpose:

The purpose of this document is to supplement the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) policies and guidelines on preparing reorganization packages. The intent of this Standard Operating Procedure (SOP) is to provide clarifying information on the reorganization process that governs the preliminary planning process (development), review/clearance process (evaluation, coordination, reprogramming procedures, review and approval), and post approval and implementation process of all reorganizations for FDA.

Guidelines:

1. HHS General Administration Manual 8-60, Reorganization Procedures and Guidance;
2. HHS General Administrative Manual 8-100, Delegations of Authority and Guidance;
3. Staff Manual Guide 1005.1, Organizational Changes – Policy and Procedures; and
4. Staff Manual Guide 1415.5, Authority to Approve Organization Structure and Functional Statements.

Preliminary Planning Process:

The Center/Office Liaison will schedule a preliminary planning meeting with the Management Analysis Services Staff (MASS) to determine if a reorganization is required. The preliminary planning meeting should include representation for the following to provide input and recommendations:

- OHR/MASS
- Center/Office Liaison
- Office of Human Resources (OHR)
    - Client Services Division's (CSD) respective Branch Chief or Designee (BC/Designee)
    - OHR Workforce Relations Division's (WRD) respective Branch Chief or Designee (BC/Designee)
- Office of Finance, Budget, and Acquisitions/Office of Budget (OB)
    - Budget Execution Staff (BES)
    - OB Budget Formulation Staff (BFS)

The following steps outline the requirements and rules for each Office in the preliminary planning process:

Step 1. (Center/Office Liaison): Prepare the following draft documents and schedule the preliminary planning meeting:

1. Executive Summary
2. Budgetary Tables
3. Current Organizational Charts
4. Proposed Organizational Charts
5. Staffing Crosswalk

Step 2. (Center/Office Liaison): The preliminary planning meeting discussions will include the major issues/concerns and with the following organizations:

OFBA BES & BFS: These two organizations will review all required documents within a reorganization package with regard to the financial part of the program activities for compliance with financial management policies and regulations; potential changes to any of the financial systems; and to determine if there is a need to notify Congress, Health and Human Services (HHS), and Office of Management and Budget (OMB) with any statutory requirements and/or reprogramming of funds. The following criteria will be used when making this determination:

1. An organization with an Office operating a program, project, or activity that identifies and accompanies an Appropriation Act for reprogramming funds to reorganize Offices in excess of $500,000 or 10%, whichever is less. Appropriations Committee requires 15 days advance notice; however, all reprogramming requests must be submitted to OB no later than May 15 in order to meet a July 1 Congressional deadline.

2. An organization created by statute or with legislative mandates requires a Congressional Notification without regard to the funding identified in Step 2, #1.

3. An organization that has been the subject of recent attention by the Appropriations Committees or has received recent adverse attention in the media. ("Recent" refers to two years or less).

Center/Office Liaison and OHR/CSD (jointly): OHR/CSD is the primary organization for all human capital resources and position management for the Agency, and assures that any changes via a reorganization or any individual action is in compliance with Agency; Department; and Office of Personnel Management policy and regulations. Therefore, the Center/Office Liaison may need to reach out to CSD Branch Chief (BC)/Designee for additional discussions/meetings after the initial preliminary planning meeting to review the required documents listed above (especially the Staffing Crosswalk document) to follow up and act on items listed below:

1. Identify which positions require establishment, abolishment, or revisions/updates to position descriptions.

2. Discuss probable impact on newly proposed or existing Senior Executive Service (SES), Senior Title 42 Science Managers, Senior Biomedical Research Service (SBRS), and flag Commissioned Corps positions.

3. Discuss potential impact on grade levels, positions, and career ladders.

4. Discuss issues that may affect Bargaining Unit Employees.

5. Discuss with CSD BC/Designee what other options may be explored or available, such as early out, buyouts, downgrades, etc.

6. Discuss procedures and time requirements to update and approve new appointments and to effect changes to positions.

7. Discuss the Union Notification requirements and process.

MASS: This organizational component is responsible for administering the Agency's reorganization program and assuring compliance with the Department's policies and procedures. Tasks involving the preliminary planning stages are listed below:

1. Discuss the appropriate organizational change (e.g., establishment, retitlement, realignment, and/or abolishment).

2. Identify the approving official for the proposed organizational changes (i.e., Secretary of Health and Human Services, Commissioner of Food and Drugs, Directorates, or Center Director) and notify the Center/Office Liaison within 2-business days.

3. Discuss any affected/applicable Delegations of Authority and the necessary changes.

4. Determine if there is a need for a Federal Register (FR) Notice. If the reorganization is deemed to affect the public, industry, academia, legislatively mandated or reprogramming of funds then the Secretary and Congressional approval required and an FR Notice will need to be prepared.

Review/Clearance Process:

Step 1. (Center/Office Liaison):

1. Based on the preliminary planning meetings and subsequent meetings with all required organizations to resolve any issues concerning the reorganization, the Center/Office Liaison will prepare the official reorganization package with all required documentation. In addition, the Center/Office Liaison will begin working with the Component Delegation Control Officer (CDCO). The CDCO will determine the affected DOAs and ensure compliance with the DOA requirements.

   The following documents listed below are required within a reorganization package:

   a. Checklist
   b. Executive Summary
   c. Requesting/Action Memorandum
   d. Clearance Record (FDA Form 2306A)
   e. Budgetary Tables
   f. Letters Notifying Congress or OMB, if applicable;
   g. Union Notification Letter
   h. Functional Statements (current and proposed)
   i. Organizational Charts (current and proposed)
   j. Organizational Charts Alternate Text (proposed)
   k. Staffing Crosswalk
   l. Draft Federal Register Notice, if applicable

2. Obtains internal clearance signatures from Center/Office Director requesting the reorganization on the Requesting/Action Memorandum and Clearance Record. Submit all applicable documents to MASS, electronically to the following e-mail address OO-Reorganization@fda.hhs.gov and in hard copy. Note: the signature requirements for the Requesting/Action Memorandum are as listed in the table below:

REQUESTING OFFICIAL	APPROVING OFFICIAL
Commissioner of Food and Drugs	Secretary of Health and Human Services
Deputy Commissioners & Chief Scientist	Commissioner of Food and Drugs
Center/Office Directors	Deputy Commissioners & Chief Scientist
Office Director	Center Director

Step 2. Management Analysis Services Staff (MASS):

1. Upon receipt of the hard copy of the reorganization package, MASS will conducts a cursory review within 1 business day to determine all required documents are included. Once this is completed, MASS will acknowledge and send a notification of receipt for the reorganization package via e-mail to the submitting Center/Office Liaison.

2. If any documentation is missing, the entire package will be returned to Center/Office Liaison and must be resubmitted will all required documentation.

3. Reorganization packages will be reviewed within 5-7 business days to ensure compliance with all applicable policies and procedures. If no deficiencies or revisions are necessary, the review/clearance process will be initiated.

4. Reorganization packages will be scanned and sent electronically for clearance approval to Budget Execution Staff (BES), Budget Formulation Staff (BFS) and OHR/Client Services Division (CSD) Branch Chief (BC)/Designee and OHR/Workforce Relations Division (WRD) BC/Designee. Each Office will have 5-7 business days (counted concurrently) to clear/approve the reorganization package. Note: larger reorganization packages will require additional clearance time of 5-10 business days (counted concurrently). **Offices that have not given their concurrence within 5-10 business days, concurrence will be deemed and the package will be submitted through the final approval process.**

Step 3. Office Human Resources (OHR):

1. The WRD BC/Designee, CSD BC/Designee, and OHR Director will have 5-7 business days each (counted concurrently) to clear/approve the reorganization package. Note: larger reorganization packages will require additional clearance time of 5-10 business days (counted concurrently). If additional time is needed of more than 5-10 business days, OHR must request an extension through MASS.

Step 4. Budget Execution Staff (BES), Budget Formulation Staff (BFS):

1. If Congressional notification is required, BES and BFS will coordinate with the Center/Office to finalize the Congressional letter(s), through the appropriate HHS Offices.

2. If Congressional notification is required, then a Congressional Notification and FR Notice must be prepared for the Secretary of Health and Human Service's approval and submitted to Congress. Note: A Congressional

Notification requires a 15-day comment period to expire before any reorganization may be finalized for publication in the FR Notice.

Step 5. Regulations Editorial Section (RES), Office of Policy (OP), Office of Policy and Planning (OPP), Office of the Commissioner (OC):

1. This organizational component is responsible for assuring all FR Notices are formatted correctly, in compliance with Agency policy and procedures, and approved by the appropriate official prior to submission to the Office of the Federal Register for publication.

2. The requirement of a FR Notice is determined during the preliminary planning meeting phase. If determined necessary, the Center/Office will prepare the FR Notice to include in the reorganization package. Note an FR Notice will be required if the organizational change is legislatively mandated or has significant interest from the public.

3. MASS will review and forward the "draft" FR Notice to RES for review during the clearance/review process.

4. Upon final approval of the reorganization, RES will finalize the FR Notice, obtain approval, and arrange for its publication. Note: the actual publication will take approximately two weeks.

Step 6: MASS:

1. Consolidates/verifies that all necessary clearances have been obtained.

2. Finalizes the official clearance record by adding the effective date for the reorganization package.

3. Submits the reorganization package to the authorized approving official for signature via e-mail or inter-office mail.

Step 7: Authorized Approving Official(s):

1. The authorized approving official (i.e., the Secretary of Health and Human Services, Commissioner of Food and Drugs, Deputy Commissioner/Chief Scientist, or Center Director as previously determined), by virtue of his/her signature, is approving the reorganization request, and the effective date is based upon that signature and date.

   Note: Although the request for reorganization has been approved, no movement of employees or filling of positions in the new organization can occur until the Standard Administrative Codes (SACs) are keyed into the personnel database.

Post Approval and Implementation Process:

Step 1. MASS:

Upon receipt of the approved reorganization package, will be monitoring the implementation of all approved reorganizations by:

1. Prepare the Notification of Approval (NOA) to assign the Standard Administrative Codes (SACs) for the new organization(s).

2. Finalizes the official Staff Manual Guides (SMGs) by ensuring that the functional statements, organizational charts, and alternate text documents reflect the approval date of the official reorganization package.

3. Verifies that the SACs have been approved and entered into the Capital HR data base and:

    - Forwards the final NOA and all related documents for the reorganization to the Center/Office Liaison, Budget Execution Staff (BES), Budget Formulation Staff (BFS), and Client Services Division (CSD) Ranch Chief (BC)/Designee; and

    - Submits the final SMGs to the Paperwork Reduction Act and Records Management Staff for publication on Agency websites.

4. Monitors the processing of the Staffing Crosswalks, publication of SMGs, and FR Notices (if applicable).

5. Ensures the affected DOAs are approved and published within the required 90-day implementation period.

6. Resolves any system or implementation issues.

7. Provides status reports to the appropriate officials.

Step 2. BES:

Verifies all funding (payroll & operating), establishes the new CAN numbers, re-allocate any reprogramming of funds, if necessary, and notifies the Centers/Office Budget Contact with the new CANs.

Step 3. Center/Office Liaison:

Formally communicate the reorganization approval to employees and outline an implementation schedule. Collaborate with CSD BC/Designee to ensure the following activities are completed within the required 90-day implementation period:

1. Receives the new CANs from the Center/Office Budget Contact;

2. Processes, update the revised and/or new position descriptions and OF-8s as necessary;

3. Finalizes the Staffing Crosswalks by updating employees information, new CANs and new SACs, and submit to CSD BC/Designee for processing realignment actions via email and cc MASS; and

4. Processes all applicable personnel actions associated with the reorganization.

    - Promotion actions do not normally result from reorganizations, with the exception of career ladder promotions; and

    - Higher graded opportunities resulting from a reorganization must be filled through the competitive process. As a result, the Center/Office Liaison will need to coordinate with CSD BC/Designee on vacancy announcements.

      Note: Should any change to lower grade situations be necessary, these must be discussed and approved prior to the implementation of the reorganization with CSD BC/Designee and MASS. Employees, who are offered change to lower grade positions, have certain rights and entitlements and specific required procedures must be followed prior to the implementation of the reorganization.

5. Ensures all affected employee records are in Capital HR, EASE, ITAS, and Gov Trip have been updated to reflect the new reorganization.

6. Check Capital HR to verify the accuracy of all actions, initiate any necessary error corrections, and verify corrections have been completed.

7. As appropriate to the reorganization, all affected Delegations of Authority must be completed within 90 days after the approval date for the reorganization. Prepare all Delegation documents according to procedures prescribed in General Administration Manual Chapter 8-100, “Delegation of Authority” and submit to MASS for review and processing.

Step 4. CSD:

1. Processes the movement of employees to new positions and to new SACs.

2. Verifies the completion of the personnel realignments

MASS Contacts:

Rodolfo Guillen	301-796-4069
Paula Longhi	301-796-8845
Danielle Williams	301-796-8850
Vanessa Starks	301-796-8846