MANAGEMENT

POLICIES AND PROCEDURES FOR ORGANIZATIONAL CHANGES

CONTENTS

PURPOSE This MAPP outlines the policies and procedures for the development, evaluation, coordination, review, and approval of organizational changes within the Center for Drug Evaluation and Research (CDER).

REFERENCE

FDA Staff Manual Guide 1005.1, *Policy and Procedures Regarding Organizational Changes*, January 23, 1995.

DEFINITIONS

- **Organizational change**. Also, referred to as a reorganization, includes the establishment, abolishment, transfer, consolidation, or name change of an organizational component, or addition, modification, abolishment, or transfer of a function(s) to, from, or within an organizational component.

- **Organizational component**. Refers to any part of the organization separately established as an organizational entity by law, regulation, the Commissioner, Food and Drug Administration (FDA), or an official who has been delegated authority and has assigned functions or an area of responsibility and has an approved Standard Administrative Code (SAC) and title.

- **Kite**. Allows a division to exceed its full time equivalent (FTE) position allotment, as long as the office above it is within its FTE limit. FTEs are borrowed from another division/office within the same office with the understanding that if in the future the losing division/office needs the FTE back, it will be replaced through attrition.

POLICY

- The objective of an organizational change is to enhance productivity and effectiveness in accomplishing the current and long-range goals of the organizational component. A proposed reorganization should be justified on the basis of these considerations.

- Organizational changes must use structures that provide efficient and effective means for accomplishing assigned functions within the bounds of available resources.

- Personnel impacts on affected organizational components must be considered and evaluated in the early stages of the organizational change. Adversely affected employees and personnel structure are the most frequently encountered problems associated with organizational changes. Therefore, it is important to resolve these issues early on.

- Constraints such as budget limitations, position management, and hiring and promotion restrictions must be considered in proposing organizational changes.

- Even a minor organizational change, e.g., a change in an organization's functions, requires an organizational change proposal.

- Excluding immediate offices, all official components must be composed of a minimum of 10 FTEs.

- The supervisor to employee ratio must be 1 supervisor to at least 10 non-supervisory employees (1:10 ratio) in each official component, i.e., branch, division, etc. Exceptions for special cases will be considered with appropriate justification provided by the affected component(s).

- The Division of Personnel Operations I (DPOI), Office of Human Resources and Management Services (OHRMS), cannot delay a proposal if there is disagreement with <u>proposed</u> grade levels. Rather, they can note their concern on the clearance record. However, if <u>current</u> grade levels are adversely affected, DPOI is not required to concur.

- Information describing and justifying all aspects of proposed organizational changes must be included in the reorganization package.

- Organizational changes at the division level and below can be approved by the Center Director.

- Organizational changes at the office level and above must be approved by the Deputy Commissioner for Operations, Food and Drug Administration (FDA).

- The effective date for the organizational change is the date of signature of the approving official.

RESPONSIBILITIES

Senior management from the affected component(s)

- Consults with DPOI, the Program Management Services Branch (PMSB) of the Division of Management Services (DMS), and if necessary, the Director and Deputy Director, Office of Management (OM), to determine the most effective structure for the affected organizational component(s) and to resolve problems such as adversely affected employees.

The Management Officer, or Program Specialist if delegated as such, of the affected component

- Provides management with staffing information including the types of positions and number of employees needed for the most effective operation of the component.

- Ensures that proposed grade structures are appropriate, and if necessary, suggests employee reassignments to assure that all affected components are able to complete their functions without causing undue hardship on the employees.

- Develops new or revised position descriptions as necessary.

- Serves as a liaison between the affected component(s) and DPOI and PMSB.

- Alerts DPOI and PMSB of anticipated problems such as adversely affected personnel.

- Provides PMSB with the following:

    1. Documentation stating the purpose of the change and a justification in terms of sound organizational criteria, and the circumstances which make the change desirable or necessary;

    2. Staffing charts depicting the current and proposed location of employees;

    3. Organizational charts illustrating the structure of the organization;

    4. New or revised functional statements (for division level and above) if functions change as a result of the reorganization; and

    5. If applicable, a brief statement of the impact on other components.

- If necessary, prepares a Request for Personnel Action (SF-52) or a realignment package for personnel changes and to change SACs once the approved reorganization package is received from PMSB.

- Forwards SF-52s or a realignment package and any other personnel actions to PMSB for review and authorizing signature.

The Management Officer of the affected component

- Reviews FTE positions allotted to the affected component(s) and informs management if the proposed staffing requirements exceed the FTEs allotted to that component. At management's request, the Management Officer will arrange a kite which allows a division to exceed its FTE allotment, as long as the office above it is within its FTE limit. The shifting of FTEs is done informally with, at most, a memo to the Director, OM, explaining the situation.

The Program Management Services Branch

- Informs OM of proposed organizational changes in the initial stages of development.

- Meets with management from the affected component(s), the Program Specialist and/or Management Officer, and DPOI to obtain all necessary information and provide information and advice on structuring the new or changed component(s).

- Informs DPOI and the Division of Management Systems and Policy (DMSP), OHRMS, of upcoming organizational changes.

- Works closely with DPOI on organizational changes at the office level and above to assure full consideration of personnel impact. At the division level and below, preliminary consultation with DPOI is encouraged but not required.

- If necessary, rewrites functional statements to make them as general and broad as possible.

- Prepares an informal reorganization package for organizational changes at or above the office level (for submission to DMSP); or prepares a formal reorganization package for organizational change at or below the division level (for approval by the Center Director). Formal reorganization packages must include:

  1. A Note to the Director, OM, briefly explaining and justifying requested changes;

  2. A Clearance Record (Form FDA 2306);

  3. A list of impact statements, i.e., supervisory ratios that may be affected and other impacts and/or concerns;

  4. Functional statements (for division level and above);

  5. Staffing charts;

  6. Organization charts;

  7. A memorandum to DMSP from the Center Director, requesting the change; and

  8. A Checklist (Form FDA 2620).

  In addition to the information listed above, informal reorganization packages must include:

  1. A new or revised Federal Register notice (in the proper format); and

  2. A memorandum to the FDA Deputy Commissioner for Operations from the FDA Deputy Commissioner for Management and Systems,

describing the reason for the reorganization and indicating that all personnel issues have been addressed, e.g., supervisory ratios.

- Routes the proposed reorganization package to the affected component(s), the Director, DMS, the Director, OM, and the Director, CDER, to obtain clearance/approval.

- Forwards a *copy* of the reorganization package to DPOI, before the original goes to DMSP, for clearance of organizational changes at or below the division level. This expedites the reorganization process by allowing DPOI time to resolve personnel issues while the original package is being sent through other channels.

- Forwards the completed original reorganization package to DMSP for review and Agency/Department approval.

- Forwards a copy of the approved package to the Management Officer to change SACs and process personnel actions.

- Authorizes SF-52s and realignment packages for the Director, OM, and forwards them and any other personnel actions to DPOI for processing.

- Maintains a file of all approved CDER reorganization packages.

The Director, Office of Management, CDER

- If necessary, meets with management of the affected component(s), Program Specialists and/or Management Officers, and PMSB to determine the most effective structure for the affected organizational component(s) and to resolve problems such as adversely affected employees. Normally, OM does not get involved until the proposal package reaches the Office for review and clearance.

- Reviews the proposed reorganization package to ensure that issues concerning personnel structure and adversely affected employees have been acknowledged, and either resolved or noted that they are being addressed.

The Center Director

- Approves or disapproves Center organizational changes at the division level and below. Approval/disapproval should be based on whether or not the organizational change enhances productivity and effectiveness in accomplishing the current and long-range goals of the organizational component and the

mission of the Center.

The Division of Personnel Operations I, OHRMS

- Provides managers and PMSB with staffing assistance and works with them to resolve personnel problems.
- Reviews personnel information contained in reorganization packages.
- Classifies new positions.
- Clears proposed reorganization packages at the division level and below before they are forwarded to DMSP, and clears DMSP's formal reorganization packages at the office level and above, indicating that personnel issues have been considered.
- Upon final approval of the reorganization package, processes realignments and other personnel actions, if necessary.

The Division of Management Systems and Policy, OHRMS

- Provides advisory, analytical, and administrative support for organizational changes in the Center. If requested, DMSP will provide support for analytical studies of organizational mission, structure, and workload.
- Evaluates reorganization proposals to ensure consistency with established FDA structure and sound organizational and management practices, and to ensure that all unresolved issues are settled before a formal proposal is forwarded to FDA for approval.
- Prepares a formal reorganization package for organizational changes at or above the Office level (for the Deputy Commissioner's approval).
- Assigns SACs to the reorganized component(s) after the organizational changes are approved at the appropriate level.
- Forwards copies of the Notification of Organization Approval and/or Standard Administrative Code Assignment (Form FDA 2755) to the appropriate Agency and Center components.
- Maintains a file of all approved CDER reorganization packages.

REORGANIZATION PACKAGE CONTENTS

- **The Clearance Record (Form FDA 2306)**. The following information must be included on the clearance record before the reorganization package is forwarded to DMSP:

  1. The current and proposed supervisory ratio for each Division/Office affected by the reorganization;

  2. A streamlining statement stating whether or not the ratio has improved. If the ratio has not improved, include a justification, i.e., "Although the Office ratio is not 1:10, it will not impact the overall ratio of the Center..."; and

  3. Clearance signatures of the Chief, PMSB; Director, DMS; Director, OM; Team Leader, DPOI; the head of the component(s) requesting the change; and at least one hierarchy above all affected components.

- **Functional Statements**. Functional statements should be as general and broad as possible so that the need for future changes are less frequent. Functional statements should be forwarded to the affected Offices and Divisions for comments and revisions before clearance is obtained. New and revised functional statements should be saved on a disk or converted from WordPerfect to e-mail and sent to DMSP. Functional statements are eventually published in the FDA Staff Manual Guide.

- **Proposed Staffing Charts**. Staffing charts in table format, showing the staffing configuration of both the original and the proposed components, are included for DPOI and DMSP. A complete breakdown of the staff must be shown, including groups, teams, etc. The chart should include the name of each employee, vacancy, and proposed position, position title, pay plan, position series, current grade, proposed grade, and the name or SAC for the organization where the employee is currently assigned. PMSB acquires this information from the Program Specialists and/or Management Officers, ARIES reports, and/or managers. An "As of" date should be shown under the title of the chart.

- **Proposed Organization Charts**. Organization charts are included in the proposed package to illustrate the complete breakdown of all affected components of the new organization.

- **Federal Register notice and related memoranda**. A new or revised Federal

Register notice (in the proper format) and a memorandum to the FDA Deputy Commissioner for Operations from the FDA Deputy Commissioner for Management and Systems is included in reorganization packages at or above the division level. The memorandum should describe the reason for the reorganization and indicate that all personnel issues have been addressed, e.g., supervisory ratios.

APPROVAL AUTHORITY

Level of Organizational Changes	**Approval Authority**
Division level and below	Center Director, Deputy Center Directors, or the Center Executive Officer
Office and Center level	FDA Deputy Commissioner for Operations

EFFECTIVE DATE

This MAPP is effective upon date of publication.