OFFICE OF 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*.
- FDA Staff Manual Guide 1415.5, *Authority to Approve Organization Structure and Functional Statements*.

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 or functions 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 or office within the same office with the understanding that if in the future the losing division or 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 must 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 (e.g., branch, division). Exceptions for special cases will be considered with appropriate justification provided by the affected components.

- The Rockville Human Resources Center (RHRC), Client Services Division, CDER Team, cannot delay a proposal if there is disagreement with ***proposed*** grade levels. Rather, they can note their concern on the clearance record. However, if ***current*** grade levels are adversely affected, RHRC 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 office/division level and below can be approved by the Center Director.

- Organizational changes at the Super Office level and above must be approved by the Commissioner, 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) will:

- Consult with RHRC, the Program Management Services Branch (PMSB) of the Division of Management Services (DMS), and, if necessary, the 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 will:

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

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

- Develop new or revised position descriptions as necessary.

- Serve as a liaison between the affected component(s) and RHRC and PMSB.

- Alert RHRC and PMSB of anticipated problems, such as adversely affected personnel.

- Provide PMSB with the following information:

    1. Documentation stating the purpose of the change, 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, prepare individual or mass realignment documents for personnel changes and to change SACs once the approved reorganization package is received from PMSB.

- Enter individual actions into the Enterprise Human Resource and Payroll System (EHRP) or forward

mass realignment package and any other personnel actions to PMSB for review and authorizing signature.

- Provide PMSB with copies of PHS Form 1662 (Request for Personnel Action — Commissioned Officer) to realign Commissioned Corp personnel affected by the reorganization.

The Management Officer of the affected component will:

- Review FTE positions allotted to the affected component(s) and inform 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 will:

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

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

- Inform RHRC and the Division of Management Systems (DMS), Office of Management Programs (OMP), of upcoming organizational changes.

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

- If necessary, work in conjunction with management to rewrite functional statements to make them as general and broad as possible.

- Prepare an informal reorganization package for organizational changes at or above the Super Office level (for submission to DMS, OMP); or prepare a formal reorganization package for organizational change at or below the Office or 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. Proposed and current staffing charts;

6. Organization charts;

7. A memorandum to DMS 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:

- A memorandum to the FDA Commissioner from the Associate Commissioner for Management and Chief Financial Officer describing the reason for the reorganization and indicating that all personnel issues have been addressed (e.g., supervisory ratios). This memorandum also requires the following concurrences: FDA, Organization Program Officer; Director, Division of Management Systems; Director, Office of Management Programs; and Director, Office of Executive Secretariat.

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

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

- Forward the completed ***original*** reorganization package to DMS, OMP, for review and Agency/Department approval.

- Forward a ***copy*** of the approved package to the Management Officer to prepare documentation to change SACs and process personnel actions.

- Authorize the actions for EHRP and realignment packages for the Director, OM, and forward them and any other personnel actions to RHRC for processing.

- Maintain a file of all approved CDER reorganization packages.

The Director, Office of Management, CDER, will:

- If necessary, meet 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.

- Review the proposed reorganization package to ensure that issues concerning personnel structure and

adversely affected employees have been acknowledged and either resolved or it is noted that they are being addressed.

The Center Director will:

- Approve or disapprove Center organizational changes at the Office or Division level and below. Approval or 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 Rockville Human Resources Center (RHRC), Client Services Division will:

- Provide managers and PMSB with staffing assistance and work with them to resolve personnel problems.

- Review personnel information contained in reorganization packages.

- Classify new positions.

- Clear proposed reorganization packages at the division level and below before they are forwarded to DMS and OMP, and clear DMS's formal reorganization packages at the office level and above, indicating that personnel issues have been considered.

- Upon final approval of the reorganization package, process realignments and other personnel actions, if necessary.

The Division of Management Systems, Office of Management Programs will:

- Provide advisory, analytical, and administrative support for organizational changes in the Center. If requested, DMS will provide support for analytical studies of organizational mission, structure, and workload.

- Evaluate 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.

- Prepare a formal reorganization package for organizational changes at or above the Super Office level (for the Deputy Commissioner's approval).

- Assign SACs to the reorganized component(s) after the organizational changes are approved at the appropriate level.
- Forward copies of the Notification of Organization Approval and/or Standard Administrative Code Assignment (Form FDA 2755) to the appropriate Agency and Center components.

- Maintain 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 DMS:

    1. The current and proposed supervisory ratio for each Division and 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 affect the overall ratio of the Center..."); and

    3. Clearance signatures of the Chief, PMSB; Director, DMS; Director, OM; Team Leader, RHRC; 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 the need for future changes is 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 in WORD for e-mail and sent to DMS. Functional statements are eventually published in the FDA Staff Manual Guide.

- **Current and Proposed Staffing Charts**. Staffing charts in EXCEL table format, showing the staffing configuration of both the original and the proposed components, are included for RHRC and DMS. A complete breakdown of the staff must be shown, including groups or teams. The chart should include the name of each employee, vacancy, 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, Management Officers, or managers. An "As of" date should be shown under the title of the chart.

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

APPROVAL AUTHORITY

Level of Organizational Changes	Approval Authority
Office and Division level and below	Center Director, Deputy Center Directors, or the Center Executive Officer
Super Office and Center level	Commissioner, Food and Drug Administration

EFFECTIVE DATE

This MAPP is effective upon date of publication.