

MANAGEMENT

CHANGES TO CDER PROGRAM DELEGATIONS OF AUTHORITY

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PURPOSE This MAPP sets forth Center for Drug Evaluation and Research (CDER) policy and procedures for establishing or making changes to the Center's program delegations of authority. CDER program delegations of authority are redelegations of authority from the Commissioner of Food and Drugs to various CDER officials. They are issued as Agency regulations in Part 5 of Title 21 in the Code of Federal Regulations (21 CFR Part 5).

BACKGROUND

Most changes that are made involve revising the position titles and organizational components to which CDER program delegations of authority apply. In other cases, additional positions and management levels are added to the delegations in an effort to streamline and decentralize decision making and approval authority in accordance with the National Performance Review initiatives.

REFERENCES

- CDER MAPP 4634.1, *CDER Program Delegations of Authority*.
- FDA Guide 1401.1, *Policy and Procedures Governing Delegations of*

Authority.

- HHS Chapter 8-100 General Administration Manual, HHS Transmittal 93.02, *Delegations of Authority*.
 - 21 CFR Chapter 1, Part 5, Subpart B, *Redelegations of Authority from the Commissioner of Food and Drugs*.
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DEFINITIONS

- **Delegation of authority.** The formal assignment or commitment of legal power, usually to a subordinate official, to make certain decisions and take certain actions that have legal significance. It generally includes the authority to sign a legal document approving the taking of action by others. It not only empowers the delegate(s) with authority but generally establishes limitations on the exercise of the authority by others. There are two types of delegations of authority: program and administrative.
- **Program authorities.** Substantive authorities contained in Acts of Congress or Executive Orders of the President that authorize programs. They authorize the taking of substantive actions such as issuing program guidelines, awarding grants and contracts, adjudicating eligibility for benefits, and analyzing applications for new drugs. Most program authorities of the Department are vested in the Secretary with the authority to redelegate.
- **Administrative authorities.** Authorize the taking of financial, personnel, or other administrative actions in support of substantive programs, either directly or indirectly.
- **CDER program delegations of authority.** Designated authorities to perform certain functions of the Commissioner of Food and Drugs which have been redelegated to particular officials in the Center. These functions involve regulatory activities such as approval of new drug applications and their supplements, granting or denying citizens petitions or issuing responses, issuance of written reports of minor violations and notices of warning, requiring a manufacturer to conduct postmarket surveillance, and granting extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs. These authorities may be carried out by persons in an official acting capacity. In most cases, they may not be further redelegated.

- POLICY**
- It is the policy of the Center for Drug Evaluation and Research to decentralize action-taking and decision-making authority as far as may be necessary to secure the most timely, economical, and effective management and administration of CDER programs and activities.
 - **Authority to Redelegate** . Any delegated authority may be redelegated totally or partially unless the delegation document or underlying legal authority prohibits or restricts redelegation. If the delegation document contains no such prohibition or restriction, the authority may be redelegated.
 - **Criteria for Making Redelegations** . The following criteria will be used to determine if redelegation is warranted:
 1. Legality: Can the delegation be legally made?
 2. Need: Will the delegation serve the objective of prompt effective administration?
 3. Economy of administration: Will the delegation eliminate a procedural step, shorten lines of communication, or otherwise save time or cost of operation?
 4. Level of responsibility: Is the position to which the authority would be delegated appropriate in terms of grade level and other assigned responsibilities?
 5. Service: Will the delegation improve services to the Department's clients?
 - **Evidence of Delegation** . Every delegation of authority should be evidenced by a document signed by the delegating official and specifying the following:
 1. The authority for making the delegation.
 2. The authority being delegated.
 3. Any limitations on the authority being delegated (e.g., scope, duration, dollar ceiling)
 4. The official title of the position to which the delegation is being

made (or for a name of a delegation, the name and official title of the person receiving the delegation).

5. Whether redelegation is permitted, and if so, what conditions or limitations apply.
6. The effective date of the delegation.
7. The date the delegation is signed.
8. The name and title of the official making the delegation.

- **Delegations by Name** . Redelegations will be made to employee by title rather than by name. Exceptions to this policy must be justified, in writing, at the time the “name” delegation is made. An authority delegated to an employee by name may not be exercised by anyone else acting for that employee.
- **Authority of Deputies** . A deputy does not automatically have the same authority as the principal. The deputy’s authority is limited to the delegations specifically given to the deputy position or the authorities the deputy may exercise when serving in an acting capacity during the absence of the principal.
- **Authority of Acting Officials** . Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity unless prohibited by the terms of the delegation, by a restriction written into the document designating him/her as “acting,” or unless not legally permissible.
- **Delegations to be Made in Writing** . Each delegation shall be made in writing in memorandum format, addressed to the positions or persons to whom the authority is being delegated, and signed by the official with the authority to make the decision.
- **Effective Date of Delegations** . Each delegation becomes effective on the date specified in the delegation document. No delegations can be made retroactively effective. However, under special circumstances, actions taken prior to the effective date may be ratified and affirmed by the delegating official with the approval of the Office of the Chief Counsel (OGC), FDA.
- **Review by Legal Counsel** . Prior to their approval, all initial delegations of

authority shall be submitted to the appropriate division of the Office of the Chief Counsel for review to ensure their legality. Redelegations of authority should also be submitted to the OGC for review whenever the official making the redelegation questions the legality of any aspect of the redelegation.

- **Publication of the Delegations** . CDER delegations of authority will be published in CDER MAPP 4634.1. Some delegations have other publication requirements.

Delegations required to be published in the Federal Register. The delegation or redelegation will be prepared for issuance as an Agency regulation in Part 5 of Title 21 (21 CFR Part 5) and forwarded to the Federal Register Writer for issuance. The delegation, as published in the Federal Register, will be reproduced in a CDER MAPP.

Delegations required to be published in an HHS Staff Manual. The delegation will be issued in a CDER MAPP and then republished, by reference, in the appropriate HHS Staff Manual.

Delegations requiring immediate action. A delegation that requires publication in less time than routine processing for publication in the usual manner will be prepared and issued by memorandum or other means to meet the emergency need. The delegation will then be processed in the usual manner to provide a permanent record of the delegation.

- **Effect of Reorganizations on Delegations** . Whenever an organization is reorganized, delegation to and within that organization may remain in effect in the successor organization, generally, unless:
 1. The reorganization document specifies otherwise.
 2. Functions upon which the delegations are based, or positions to which the delegations are made, are transferred to another organization or are abolished.
 3. Delegations that remain in effect in the successor organization generally shall be reviewed and updated not later than 90 days after the reorganization becomes effective to reflect changes in: the flow of authority to and within the organization, the functions performed by the organization, the organization's structure and nomenclature, the key positions within the organization, and any other factor

affecting the delegating authority.

RESPONSIBILITIES AND PROCEDURES

- Requests or suggestions for additional delegations of authority may be made in any area when existing delegations are not adequate or when situations arise that require new delegations of authority.
- **Management Officials are responsible for:**
 1. Making recommendations or requests for new delegations or redelegation of authority, where appropriate.
 2. Making certain that officials in his/her organization understand the substance and limits of the authorities delegated to them.
 3. Periodically reviewing delegations in effect within their organization to ensure their continued need and effectiveness.
- **The Management Analysis Branch (MAB), Division of Planning, Evaluation, and Resource Management (DPERM), Office of Management (OM), is responsible for:**
 1. Coordination of current program delegations of authority.
 2. Central coordination of requests or suggestions for new delegations or redelegations of authority from CDER officials.
 3. Advising management officials on delegations of authority, implementing Department and Agency policies and practices regarding delegations of authority, providing technical assistance, and maintaining and indexing delegations made to and within the Center.
 4. Preparation and routing of memoranda requesting new delegations or redelegations of authority.
 5. Coordinating with the FDA Delegations Control Officer, in the Organizational Planning Branch/Division of Management Systems and Policy, Office of Management and Operations, FDA, on any new delegations or redelegations of authority.

- **The Organizational Planning Branch, Division of Management Systems and Policy, Office of Management and Operations, FDA, is responsible for:**
 1. Central coordination for issuance of delegations of authority.
 2. Review and preparation of changes to delegations of authority and issuance and coordination with the Regulations Editorial Staff for publication in the Federal Register.
 3. Maintenance of the official file of all delegations of authority, both from the Secretary and from the Commissioner downward.
 - For additional information or specific guidance, you may contact MAB at (301) 827-0510.
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EFFECTIVE DATE

This MAPP is effective upon date of publication.