1. PURPOSE.

This Staff Manual Guide (SMG) sets forth the Food and Drug Administration’s (FDA) policy and procedures governing Regulatory and Administrative Delegations of Authority (DOA).

2. LEGAL IMPORTANCE OF DELEGATIONS.

Delegations of Authority are important to the operation of the Agency. Delegations allow the FDA Commissioner and other officials to convey their authorities to subordinate officials so they may legally carry out the many activities of the Agency. Carrying out these activities without legal authority could have a serious adverse impact on the Government, the Department, the Agency, and the official who acts without legal authority. For example, an official who approves an expenditure of funds without proper legal authority in writing could be held liable for the funds.

3. LEGAL AUTHORITY.

A. Authorities Reserved by the Secretary. The Secretary reserves certain authorities, including:
1. To make and issue report(s) to the President and Congress

2. To approve and issue regulations

3. To establish advisory councils and committees and appoint their members

B. Authority of the Commissioner. The Commissioner receives authority from the HHS Secretary or the Department's administrative program officials, and by statute. Redelegation of an authority is subject to the restrictions specified in the delegation memorandum issued by the Department or limitations under the law. (Note: Staff Manual Guide 1410.10 contains the FDA Commissioner’s authorities and paragraph 2 contains the Reservation of Authority.)

4. DEFINITIONS.

A. Delegation of Authority. Delegations of Authority are the formal assignment or commitment of legal power, usually to subordinate officials, to make certain decisions and take certain actions that have legal significance. It may involve regulatory authority, administrative authority, or both. DOAs are required for the performance of such functions as:

1. Regulating non-government activities.

2. Entering into contracts involving the obligation of federal funds.

3. Certifying documents and affixing the Department Seal.


5. Carrying out functions assigned specifically by law or regulations to certain officials and the exercise of which has legal significance. (Note: Certain employees of the FDA have specific general authorities based on status or positions within organizations. For example, supervisors have the authority to assign work to employees under their supervision. These authorities are defined in position descriptions, functional statements, and other official documents. This guide does not apply to these general grants of authority.)

B. Types of Authority

1. Regulatory Authorities. Regulatory authorities are contained in Acts of Congress, Executive Orders of the President, and in the Code of Federal Regulations (CFR) that authorize programs. They authorize the taking of substantive actions such as issuing program guidelines and evaluating applications for new drugs. Most regulatory authorities of the Agency are either delegated to the FDA Commissioner by the Department of Health and Human Services (HHS) Secretary or vested in the Commissioner.
2. **Administrative Authorities.** Administrative authorities govern the taking of financial, personnel, or other administrative actions in support of substantive programs, either directly or indirectly. Such actions include purchasing equipment, hiring employees, approving travel, and issuing building passes. These authorities are derived primarily from government-wide acts (such as the Administrative Procedure Act of 1946, 5 U.S.C. 551 et. seq. and the Chief Financial Officers Act of 1990, 31 U.S.C. 901 et. seq.) and from related regulations and are issued by central control agencies such as the Office of Management and Budget, the General Services Administration, and the Office of Personnel Management. These authorities generally reside in, flow through, or are coordinated by management staff offices, which report to the head of an organization. Most FDA administrative and personnel authorities flow through the Deputy Commissioner for Administration.

C. **Delegation/Redelegation.** Delegation and redelegation are acts of empowering with legal authority. The term delegation describes the initial assignment of authority, while the term redelegation describes the reassignment of the authority. Both generally include the authority to sign a legal document to approve the taking of action by others and the limitations on the exercise of the authority. (Redelegation of the authority does not divest that authority from the delegating official.)

D. **Organizational Components.** The term organizational component refers to any part of the FDA organization with the following characteristics:

1. Is separately established as an organizational entity by law, the HHS Secretary, regulation, or an official who has been delegated authority

2. Has assigned functions or area of responsibility, an organizational title, and an approved Standard Administrative Code (SAC)

E. **Rescission.** A rescission of authority is the repealing of all or part of an authority previously delegated.

F. **Requesting Official.** The party that requests an authority to be delegated to him or her. A requesting official becomes a “delegatee” upon approval of a delegation of authority.

**H. Federal Register notice.** Used by the Department and other federal agencies to legally inform the public about federal programs, activities, and organizations and the rules and regulations applicable to these programs and activities. Publication of this information is generally required by law or regulation.

**5. POLICY ON DELEGATIONS OF AUTHORITY.**

**A. General.** It is the policy of the FDA to decentralize action-taking and decision-making authority to the organizational component that will provide the timeliest, most economical, and most effective administration of Agency programs. (General criteria for making delegations are set forth in paragraph 8 of this SMG.)

**B. Delegations by Title.** Redegulations will be made to official positions in lieu of to employees 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, including the occupant’s deputy serving in an acting capacity, and becomes void when the occupant vacates the position.

**C. Authority of Deputies and Individuals Serving in a Deputy Position.** 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.

**D. 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 acting, or unless not legally permissible.

**E. 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 (or those that would have an interest), and signed by the official with the authority to make the delegation. The delegations of authority memorandum should contain the following, or other similarly worded language: “I hereby delegate to you or your successor, the authority to…” This will ensure an official has the same authority as his or her predecessor when a title changes. The contents of the memos will be published in FDA’s SMG system on the Internet and the FDA intranet to reflect the delegation.

**F. Effective Date of Delegation.** Each delegation becomes effective on the date the delegation is approved. No delegation can be made retroactively effective. Authority should not be exercised until it is officially delegated; 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 of FDA.
(Ratify and Affirm Statement: I hereby ratify and affirm any actions taken by you or your subordinate(s) that involved the exercise of the authorities delegated herein prior to the effective date of this delegation.)

G. Effect of Reorganization on Delegations. Whenever an organization is reorganized, delegations to and within that organization may remain in effect in the successor organization, generally, unless:

1. The reorganization document specifies otherwise. (Note: The reorganization document should always contain a statement as to how the reorganization affects existing delegations).

2. Functions on which the delegations are based, or positions to which the delegations are made, are transferred to another organization or are abolished. In those instances, the delegations are terminated on the effective date of the reorganization unless the reorganization document specifies otherwise.

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 delegated authority.

H. Existing DOAs. Existing DOAs should be periodically reviewed to determine if they are affected by new or amended legislation. Authorities may have to be modified, expanded, or it may be determined that they are not affected. The FDA Principal Delegation Control Officer, through consultation and verification by the Office of the Chief Counsel, can assist in making these determinations.

6. RESPONSIBLE COMPONENTS.

A. The **FDA Principal Delegation Control Officer**, under the direction of the Office of Management Programs (OMP), Office of the Commissioner, is responsible for:

1. implementing Department policies and procedures, and developing FDA policies and procedures on DOA;

2. serving as the FDA’s principal advisor on DOA;

3. providing technical assistance on DOA;

4. administering the organization’s delegation control system;
5. coordinating the review of proposed regulatory delegations submitted for approval of the FDA Commissioner and the HHS Secretary; and changes to the administrative authorities for approval by the Deputy Commissioner for Administration;

6. working with Center/Office liaisons to clarify the DOA process and to provide technical assistance in the development of DOAs (e.g., for new or amended legislation);

7. coordinating agency clearances on proposed DOA packages;

8. maintaining and indexing DOAs made to and within FDA;

9. posting of updated Staff Manual Guides to agency websites (both FDA Intranet and Internet);

10. ensuring that the officials who have been delegated authorities understand the substance and limits of those authorities; and

11. periodically reviewing existing delegations within the FDA to ensure their continued necessity and accuracy.

B. Each **Component Delegation Control Officer (CDCO)** is responsible for:

1. Serving as the component’s principal advisor on DOA.

2. Implementing Agency policies and practices on DOA.

3. Providing technical assistance on DOA within each component.

4. Working with the FDA Principal Delegation Control Officer on DOA.

5. Working with component organizations to ensure that position titles are correct and their corresponding organizational titles are officially established and assigned Standard Administrative Codes.

6. Developing proposed DOA packages and acquiring the appropriate approval signatures from component authorities within the “Owning Office”.

7. Coordinating the review of the proposed Delegation of Authority by all affected Centers and Offices. It is the responsibility of the “Owning Office” to finalize and approve any changes made to the “final” proposed DOA.

**NOTE**: When position or organizational titles are changed within their respective organizational component, CDCOs are responsible for initiating updates within 90 days to the titles in ALL administrative or regulatory delegations making reference to the
changed title, not just to those in their functional category, since multiple Centers and Offices may be reflected under more than one category.

C. FDA Managers are responsible for:

1. identifying the need for redelegating authority within their organization;
2. redelegating authority, where permitted, to subordinates and making certain that these officials understand the substance and limits of authorities; and
3. periodically reviewing delegations within their respective organization to verify their continued need and correctness.

D. Office of the Chief Counsel and the Office of Policy, Planning & Budget conduct legal and policy reviews to ensure that the delegation is appropriately prepared and delegated. The legal review ensures that the statute is appropriately cited, that the interpretation is correct, and the legality of the delegation. The policy review takes into consideration current regulations and policies related to the delegation and if other components would be impacted, and provides policy decisions on the level(s) of the redelegation(s).

E. Delegating Official Responsibilities. After signing a delegation package, the delegating official shall make certain that the delegatee has access to the policy or procedural instructions identified in the delegation that they will need to exercise the delegated authority. Where appropriate, these instructions should be provided to each delegatee within the signed delegation.

7. PUBLICATION OF DELEGATION AND REDELEGATION DOCUMENTS.

Regulatory and Administrative Delegations of Authority will be published electronically in the 1400 series of the Agency's Staff Manual Guide (SMG) system upon clearance and signature, to notify Agency components and the public of delegations or redelegations. Regulatory delegations are available in the 1410 series SMGs (i.e., 1410.100, Human Drugs; 1410.200, Biologics; 1410.400, Medical Devices and Radiological Health; etc.) on the FDA Intranet and Internet (for public access). The regulatory delegations are displayed by subject category; however, multiple Centers or Offices may be reflected under that category (i.e., Medical Devices and Radiological Health contains authorities for CDRH, CDER, and CBER). Administrative delegations are available on the FDA Intranet and the Internet (for public access) and they are categorized by subject area as well (i.e., 1415, General Administration; 1430, Personnel; 1455, Travel; etc.).

8. CRITERIA FOR ADMINISTERING REDELEGATIONS.

The following criteria will be used to determine whether redelegations are warranted:
1. **Legality:** Can the delegation be legally made?

2. **Need:** Will the delegation facilitate prompt, effective administration?

3. **Economy:** Will the delegation eliminate a procedural step, shorten lines of communication, or otherwise save time or cost of operations?

4. **Level of Responsibility:** Is the position to which the authority is to be delegated appropriate in terms of grade level and other assigned responsibilities?

5. **Funds:** Have funds been specifically appropriated to implement the authority? Or, have senior officials allocated funds to support the authority? If yes, from what source?

6. **Service:** Will the delegation improve services to the FDA’s clients?

7. **Existing procedures:** Is the delegation consistent with existing policy for implementing FDA administrative and management functions and programs?

9. **FORM AND CONTENT OF REGULATORY AND ADMINISTRATIVE DELEGATIONS.**

A. **Regulatory.** Every regulatory DOA must have a signed delegation memorandum that has been fully cleared by the appropriate functional component (generally those that would be affected, usually a Center/Office Director), Office of the Chief Counsel and the Office of Policy, Planning and Budget and signed by the Commissioner (or in some cases, the Secretary). Once the appropriate signatures have been obtained, the DOA must be included in the 1410 series of the Staff Manual Guide. Each request for a new or revised regulatory delegation should include the following:

1. A request memorandum, to the Commissioner, is required to initiate the action and a Center Director, Associate Commissioner for Regulatory Affairs, OC Office Director, or equivalent official signs that request. The memorandum must be concise, cite the authority for making the delegation, contain appropriate legal citation, and should include the reason, basis, and justification for the request [i.e., Issue, Background, and Recommendation paragraphs]. A short explanation of the authorities cited in the delegation of authority is required as well. The justification should satisfy the information under paragraphs 5 and 8 of this SMG.

2. A Clearance Record signed by the initiating official and cleared by the Office of the Chief Counsel and the Office of Policy, Planning and Budget.
3. The delegation memo from the FDA Commissioner (or the Secretary) to the appropriate agency official(s) granting the authority (i.e., Authority Delegated and To Whom Delegated), with appropriate legal references; any Limitations (i.e., exclusions, dollar thresholds, scope, etc.); redelegation language; effective date; and Ratify and Affirm statement, as necessary (Section 5F).

4. SMG (both the current, posted version and the “proposed” SMG, formatted for final approval, including History Table).

5. Appropriate background information (i.e., excerpt from the law, guidance from HHS, relevant correspondence, regulation excerpt, etc.).

B. Administrative. Every administrative DOA must have a signed delegation memorandum that has been fully cleared by the appropriate administrative official(s) (generally those that would be affected, usually a Center/Office Director) and the Office of Management Programs, and signed by the Deputy Commissioner for Administration (in certain cases, signed by the Commissioner). Once the appropriate signatures have been obtained, the DOA must be included in the 1400 series of the Staff Manual Guide. Each request for a new or revised administrative delegation should include the following:

1. A request memorandum, to the Deputy Commissioner for Administration (or Commissioner) is required to initiate the action and a Center Director, Associate Commissioner for Regulatory Affairs, OC/OA Office Director, or equivalent official signs that request. The memorandum must be concise, cite the authority for making the delegation, contain appropriate legal citation, and should include the reason, basis, and justification for the request [i.e., Issue, Background, and Recommendation paragraphs]. The justification should satisfy the information under paragraphs 5 and 8 of this SMG.

2. A Clearance Record signed by the initiating official and cleared by the Office of Management Programs.

3. The delegation memo from the Deputy Commissioner for Administration (or Commissioner) to the appropriate agency official(s) granting the authority (i.e., Authority Delegated and To Whom Delegated, with appropriate legal references; any Limitations (i.e., exclusions, dollar thresholds, scope, etc.); redelegation language; effective date; and Ratify and Affirm statement, as necessary (Section 5F).

4. SMG (both the current, posted version and the “proposed” SMG, formatted for final approval, including History Table).

5. Appropriate background information, (i.e., excerpt from the law, guidance from HHS, relevant correspondence, regulation excerpt, etc.).
10. DOA SYSTEM AND PROCEDURES.

Most regulatory authorities of the Agency are either delegated to the FDA Commissioner by the HHS Secretary or vested in the Commissioner. Authorities delegated to the Commissioner from the Secretary (and therefore needing Secretary approval) must follow guidelines found in the HHS General Administration Manual, Chapter 8-100 (issued 9/16/2009). Most administrative authorities of the Agency are issued by agencies such as the Office of Management and Budget, General Services Administration and the Office of Personnel Management and flow through Department management staff to the Commissioner. Most FDA administrative and personnel authorities flow through the Deputy Commissioner for Administration.

A. Regulatory Redelegation from the Commissioner to FDA officials resulting from new authorities, new or amended legislation or regulations, and reorganizations that include additions/changes to position titles, additions/changes to Center/Office titles, and/or additions/changes to authorities must include the following steps:

1. Proposed Staff Manual Guides are prepared by the CDCO, reflecting the new or changed regulatory Delegation of Authority (Exhibit 1). The CDCO from the component requesting the change should prepare the documentation.

2. The CDCO coordinates the review of the proposed Delegation of Authority by all affected Centers and Offices. It is suggested that all affected components give input to the revision. It is the responsibility of the “Owning Office” to approve any changes made to the proposed DOA.

3. The CDCO prepares the Regulatory Request for Approval Memorandum to the Commissioner (Exhibit 2) and obtains the “Owning Office” signing official’s signature.

4. The CDCO prepares a Clearance Record, signed by the “Owning Office” official to be cleared by the Office of the Chief Counsel and the Office of Policy, Planning and Budget (Exhibit 3).

5. The CDCO prepares the Regulatory Memorandum Granting Approval from the FDA Commissioner and addressed to Center Executive Officers, CDCOs and the Director, Office of Management Programs (Exhibit 4).

6. The CDCO includes copies of the appropriate section or excerpt from the Act or public law.

7. The signed package is forwarded to OMP, who obtains clearance from Office of the Chief Counsel and the Office of Policy, Planning and Budget.

8. Once cleared, the package is sent to the Commissioner for signature.
B. Administrative Redelegations from the Deputy Commissioner for Administration to FDA officials, are usually initiated by an administrative component (i.e., Office of Financial Operations, Office of Information Management, Office of Shared Services, etc.) resulting from changes in Agency policy or guidance and must include the following steps:

1. Proposed Staff Manual Guides are prepared by the CDCO reflecting a new or changed administrative delegation of authority (Exhibit 5). The CDCO from the component requesting the change should prepare the documentation.

2. The CDCO coordinates the review of the proposed Delegation of Authority by all affected Centers and Offices. It is suggested that all affected components give input to the revision. It is the responsibility of the “Owning Office” to approve any changes made to the proposed DOA.

3. The CDCO prepares the Administrative Request for Approval Memorandum (Exhibit 6) and obtains the “Owning Office” signing official’s signature.

4. The CDCO prepares a Clearance Record, signed by the “Owning Office” official to be cleared by the Office of Management Programs (Exhibit 7).

5. The CDCO prepares the Administrative Memorandum Granting Approval addressed to all officials affected by the delegation. (Exhibit 8).

6. The CDCO includes any applicable background materials or guidance, which prompted the change.

7. The signed package is forwarded to OMP for clearance.

8. Once cleared, the package is sent to the Deputy Commissioner for Administration for signature.

11. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on January 20, 2011.
### Document History - SMG 1401.1, Policy and Procedures Governing Regulatory and Administrative Delegations of Authority (DOAs)

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SMG 1234.5

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY – (include series name here in caps)

(include subject name of DOA here in caps)

Effective Date:

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

2. LIMITATIONS.

A. (Heading 2)
   1. (Heading 3)
      a. (Heading 4)
         (1) (Heading 5)
            (a) (Heading 6)
               i. (Heading 7)

3. REDELEGATION.

4. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on

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01/20/2011
Date: [Insert date of signature]
To: Commissioner of Food and Drugs
From: [Insert title of Owning Center/Office Director]
Subject: [Insert title of SMG], (Referenced in SMG [Insert SMG #])

ISSUE
[Insert paragraph describing the reason for amending the delegation and the specific changes being made to the SMG].

BACKGROUND
[Insert background information, including the reason, basis and justification for the request as well as a summary of the authorities granted].

RECOMMENDATION
I recommend that you approve the attached Delegation of Authority memorandum.

[Insert name of signing official].
DATE:

TO: See Addressees Below

FROM: Commissioner of Food and Drugs

SUBJECT: Delegation of Authority [Insert title of SMG], (Referenced in SMG [Insert SMG #])

I hereby delegate to you or your successor:

AUTHORITIES DELEGATED.

[Insert specific authorities being granted.]

TO WHOM DELEGATED.

[Insert specific positions to which the authorities are being delegated.]

LIMITATIONS

[Insert limitations to the authorities, if any exist.]

REDELEGATION.

These officials [insert whether this may or may not be redelegated] further redelegate this authority.

EFFECTIVE DATE.

These delegations become effective upon date of signature. In addition, I hereby ratify and affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

Margaret A. Hamburg, M.D.

Addressees:

Center Executive Officers
Center Delegations Liaisons
Director, Office of Management Programs

01/20/2011
SMG 1234.5

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

ADMINISTRATIVE - GENERAL ADMINISTRATION

(include subject title of DOA here in caps)

Effective Date: mm/dd/yyyy

1. AUTHORITIES DELEGATED.

2. TO WHOM DELEGATED.

3. LIMITATIONS.

   A. (Heading 2)

      1. (Heading 3)

         a. (Heading 4)

            (1) (Heading 5)

            (a) (Heading 6)

            i. (Heading 7)

4. REDELEGERATION.

5. EFFECTIVE DATE.

The Deputy Commissioner for Administration approved this delegation, via memorandum on

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01/20/2011
Date: [Insert date of signature]

To: Deputy Commissioner for Administration

From: [Insert title of Initiating Office Director]

Subject: [Insert SMG Title], (Referenced in SMG [Insert SMG #]

ISSUE

[Insert paragraph describing the reason for amending the delegation and the specific changes being made to the SMG].

BACKGROUND

[Insert background information, including the reason, basis and justification for the request as well as a summary of the authorities granted].

RECOMMENDATION

I recommend that you approve the attached Delegation of Authority.

[Insert name of signing official].
DATE:

TO:            See Addressees Below

FROM:        Deputy Commissioner for Administration

SUBJECT:      Delegation of Authority [Insert title of SMG] (Referenced in SMG [insert SMG #]

I hereby delegate to you or your successor:

**AUTHORITY DELEGATED.**

[Insert specific authorities being granted.]

**TO WHOM DELEGATED.**

[Insert specific positions to which the authorities are being delegated.]

**LIMITATIONS.**

[Insert limitations to the authorities, if any exist.]

**REDELEGATION.**

These officials [insert whether this may or may not be redelegated] further redelegate this authority.

**EFFECTIVE DATE.**

These delegations become effective upon date of signature. In addition, I hereby ratify and affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

[Signature]
[Name]

Addressees:

Center Executive Officers
Center Delegations Liaisons
Director, Office of Management Programs

01/20/2011