

SMG 1415.5

**FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF
AUTHORITY**

ADMINISTRATIVE - GENERAL ADMINISTRATION

**AUTHORITY TO APPROVE ORGANIZATION STRUCTURE AND
FUNCTIONAL STATEMENTS**

Effective Date: March 21, 2013

1. AUTHORITY DELEGATED.

To approve all reorganization proposals within FDA, except as reserved in Limitations below.

2. TO WHOM DELEGATED.

Third echelon and below reorganization proposals, except as noted below in Section 3, Limitations, are redelegated to the positions listed below, and subject to prior review and concurrence by the Director, Management Analysis Services Staff:

- A. Deputy Commissioners and Chief Scientist
- B. Center Directors, Associate Commissioner for Regulatory Affairs
- C. Deputy Chief Operating Officer

3. LIMITATIONS.

The Secretary has retained the authority to approve all reorganizations that involve the following:

- A. More than one operating division (OPDIV). This would include the transfer of a function, program, or component from one OPDIV to another.
- B. A statutorily based organization. This would include:
 - 1. The establishment of an organization unit which must be approved by Congress;
 - a. The abolition of a statutorily based organizational unit; and
 - b. The elimination of a function mandated to be included in such an

organizational unit.

- c. A significant reorganization which may affect the public. This could, for example, include the reorganization of multiple offices within the Commissioner's office or a Center or a realignment of functions that have a direct impact on the public.
- d. For reorganizations going to the Secretary for approval, if no decision is made within 30 days of receipt in the Office of the Secretary (except for a reorganization requiring Congressional approval), the OPDIV Head may approve the reorganization. For reorganizations involving more than one OPDIV, both OPDIV Heads must approve the reorganization before it becomes effective.

The Commissioner retains the authority to approve all first and second echelon reorganizations except, as noted above in Section 3A, Limitations.

4. REDELEGATION AND CERTIFICATION.

These authorities may not be redelegated.

5. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on March 21, 2013.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	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	04/29/2010	N/a	OC/OA/ OM/OMP	Dr. Margaret Hamburg, Commissioner FDA
Revision	03/21/2013	N/a	OO/OHR/MASS	Dr. Margaret Hamburg, Commissioner FDA