

SMG 1410.25

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

AUTHORITY RELATING TO TECHNOLOGY TRANSFER

Effective Date: May 6, 2013

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

A. The following official is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under §11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended:

1. Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).

B. The following officials are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) requested by the Commissioner under the Act (15 U.S.C. 3701 et seq.), as amended, and Executive Order 12591 of April 10, 1987 (except to the extent that redelegation of those functions is specifically limited in the delegation of authority referenced in SMG 1410.10, paragraph 10(a)(26)), as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory Directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner to require that agreements entered into under §11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with §11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A)):

1. Deputy Commissioners and Chief Scientist.
2. Center Directors and Associate Commissioner for Regulatory Affairs.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on May 6, 2013.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/04/2010	N/a	OC/OA/ OM/OMP	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	05/06/2013	N/a	FDA/OGROP /ORM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs