

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – General Redelegation of Authority

Technology Transfer

Effective Date: 2 June 2025

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to perform the functions of the Commissioner of Food and Drugs (the Commissioner), under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*) (the Act), as amended, and Executive Order 12591 of April 10, 1987 (except to the extent that redelegation of those functions is specifically limited in the Delegations of Authority to the Commissioner (SMG 1410.10, section 1.A.(30)), 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 disapprove or require the modification of agreements under section 12(a) of the Act (15 U.S.C. 3710a(a)) presented to the Commissioner in accordance with section 12(c)(5)(A) and (B) of the Act (15 U.S.C. 3710a(c)(5)(A) and (B)):

- (1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.
- (2) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.
- (3) Center for Devices and Radiologic Health (CDRH) Director and Deputy Directors.
- (4) Center for Tobacco Products (CTP) Director and Deputy Director.
- (5) Center for Veterinary Medicine (CVM) Director and Deputy Directors.
- (6) Human Foods Program (HFP) Deputy Commissioner for Human Foods.
- (7) Office of the Chief Scientist (OCS) Chief Scientist.
- (8) OCS/FDA Technology Transfer Program Staff (FTTPS) Director.
- (9) OCS/National Center for Toxicological Research (NCTR) Director and Deputy Director.
- (10) Office of Digital Transformation (ODT) Chief Information Officer.
- (11) Office of Inspections and Investigations (OII) Associate Commissioner for Inspections and Investigations and Deputy Associate Commissioner for Inspections and Investigations.

(12) Office of Operations (OO) Deputy Commissioner for Operations & Chief Operating Officer and Deputy Chief Operating Officer.

(13) Office of Policy, Legislation, and International Affairs (OPLIA) Deputy Commissioner for Policy, Legislation, and International Affairs.

B. The officials listed below are authorized to perform the functions of the Commissioner, as requested by the Commissioner, to approve, 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 sections 12(c)(5)(A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(c)(5)(A) and (B)), as amended:

- (1) OCS Chief Scientist.
- (2) OO Deputy Commissioner for Operations & Chief Operating Officer and Deputy Chief Operating Officer.
- (3) OPLIA Deputy Commissioner for Policy, Legislation, and International Affairs.

C. The officials listed below are authorized to perform the functions of the Commissioner to administer and make decisions regarding inventions and patents and to make determinations of rights in inventions and patents in which the Department has an interest as they pertain to the authorities under 35 U.S.C 207(a) and 209, as amended, to:

- apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title or interest;
- grant non-exclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right to enforcement pursuant to the provisions of chapter 29 as determined appropriate in the public interest;
- undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract;
- transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

- (1) OCS Chief Scientist.
- (2) OCS/FTTPS Director.

D. The officials listed below are authorized to perform the functions of the Commissioner to administer and make decisions regarding inventions and patents and to make determinations of rights in inventions and patents in which the Department has an interest as they pertain to the authorities under 35 U.S.C 207(a) and 209, as amended, to apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title or interest:

- (1) OCS/FTTPS licensed patent attorneys registered to practice with the United States Patent and Trademark Office.

2. Redelegation.

These officials may not further redelegate these authorities.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 2 June 2025.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	04/02/2001	N/A	OA/ OM/ OMP	Lester Mills Crawford, D.V.M, Ph.D. Acting Commissioner of Food and Drugs
Revision	06/04/2010	N/A	OA/ OM/ OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	05/06/2013	N/A	OGROP/ ORM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	06/02/2025	N/A	OCS/ FTTPS	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs