

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

**REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY**

**ENFORCEMENT ACTIVITIES**

Effective Date: 06/04/2010

**1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.**

A. Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA-200A, Identification Record, and Form FDA-200B, Specification of General Authority, are authorized:

1. to conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 372 (e) (5)); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461), the Federal Caustic Poison Act (44 Stat. 140b; see also Public Law 86-613, section 19, formerly section 18), the Import Milk Act (21 U.S.C. 141-149), the Filled Milk Act (21 U.S.C. 61-64), and sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264); and
2. to administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

B. Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner of Food and Drugs (Commissioner) to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA-200D, Special Authority for Criminal Investigators, is authorized to do the following:

1. As set forth under section 702(e)(1) through (e)(5) of the act (21 U.S.C. 372 (e)(1)-(e)(5)):
  - a. Carry firearms
  - b. Serve and execute search warrants and arrest warrants

- c. Execute seizure by process issued under libel under section 304 of the act (21 U.S.C. 334)
  - d. Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense
  - e. Make, prior to the institution of libel proceedings under section 304(a)(2) of the act (21 U.S.C. 334(a)(2)), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable grounds to believe that they are, subject to seizure and condemnation under section 304(a)(2) of the act
2. Perform such other functions under the act, or any other law, as the Commissioner may prescribe
  3. To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953
- C. Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to provide specialized law enforcement support involving criminal investigations under the act, and other duties as assigned by the Commissioner, and issued the Food and Drug Administration Official Credential consisting of Form FDA-200E, Special Authority for Criminal Investigative Specialists, is authorized to receive information as to all matters relating to such act and regulations issued under the act.

## **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 June 4, 2010.

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