

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

Effective Date: May 14, 2015

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

- A. The following officials are authorized under section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381), to perform the following functions or to designate officials to request from the Secretary of the Treasury samples of food, drugs (including biological products), devices, cosmetics or tobacco products imported or offered for import, determine whether such articles are in compliance with the FD&C Act, authorize relabeling or other compliance actions to bring articles into compliance under the FD&C Act and supervise such compliance actions.
1. Assistant Commissioner for Operations, Office of Operations (OO), Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).
 2. Regional Food and Drug Directors and District Directors, OO, ORA, OGROP.
 3. Director, Office of Enforcement and Import Operations (OEIO), OO, ORA, OGROP.
 4. Director, Division of Import Operations (DIO), OEIO, OO, ORA, OGROP.
 5. Director and Deputy Directors, Office of Compliance, Center for Devices and Radiological Health (CDRH).
- B. The following officials are authorized, under section 536 of the FD&C Act (21 U.S.C. 360mm), to perform the following functions or to designate officials to request from the Secretary of the Treasury samples of electronic products imported or offered for import to determine whether such products are in compliance with section 534 of the FD&C Act (21 U.S.C.360kk), refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal, supervise operations to bring noncomplying products into compliance under section 534 of the FD&C Act (21 U.S.C. 360kk), and refuse or grant permission and time extensions to bring noncomplying products into compliance with section 534 of the FD&C Act (21 U.S.C. 360kk) in accordance with a corrective action plan approved by the:

1. Director and Deputy Directors, (CDRH).
 2. Director and Deputy Directors, Office of Compliance, Office of In Vitro Diagnostics and Radiological Health (OIR) and Office of Surveillance and Biometrics, CDRH.
 3. Assistant Commissioner for Operations, OO, ORA, OGROP.
 4. Regional Food and Drug Directors and District Directors, OO, ORA, OGROP.
 5. Director, OEIO, OO, ORA, OGROP.
 6. Director, DIO, OEIO, OO, ORA, OGROP.
- C. The following officials are authorized, under section 538(b) of the FD&C Act (21 U.S.C. 360oo(b)), to exempt persons from issuing a certification, as required by section 534(h) of the Act (21 U.S.C. 360kk(h)) for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations.
1. Director and Deputy Directors, CDRH.
 2. Director and Deputy Directors, OC and OIR, CDRH.
 3. Assistant Commissioner for Operations, OO, ORA, OGROP.
 4. Regional Food and Drug Directors and District Directors, OO, ORA, OGROP.
 5. Director, OEIO, OO, ORA, OGROP.
 6. Director, DIO, OEIO, OO, ORA, OGROP.
- D. The following officials are authorized to exercise all of the functions of the Commissioner of Food and Drugs (Commissioner) under section 362 of the Public Health Service Act (42 U.S.C. 265) that relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products, tobacco products, and other items or products regulated by the Food and Drug Administration (FDA) into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the FDA.
1. Assistant Commissioner for Operations, OO, ORA, OGROP.
 2. Regional Food and Drug Directors and District Directors, OO, ORA, OGROP.

3. Director, OEIO, OO, ORA, OGROP.

4. Director, DIO, OEIO, OO, ORA, OGROP.

E. The following officials are authorized to perform all the functions of the Commissioner pertaining to exportation of medical devices under section 801(e) of the FD&C Act (21 U.S.C. 381(e)) for medical devices assigned to their respective organization.

1. Director and Deputy Directors, CDRH.

2. Director and Deputy Directors, OC, CDRH.

3. Director and Deputy Directors, OIR, CDRH.

4. Director, Office of In Vitro Diagnostics and Radiological Health, CDRH.

5. Director and Deputy Directors, CBER.

6. Director and Deputy Director, Office of Compliance and Biologics Quality, (OCBQ), CBER.

7. Assistant Commissioner for Operations, OO, ORA, OGROP.

8. Regional Food and Drug Directors and District Directors, OO, ORA, OGROP.

9. Director, OEIO, OO, ORA, OGROP.

10. Director, DIO, OEIO, OO, ORA, OGROP.

F. The following officials are authorized to perform the functions of the Commissioner for drugs under their jurisdiction, pertaining to authorizing the re-importation of prescription drugs under section 801(d)(2) of the FD&C Act (21 U.S.C. 381(d)(2)) for emergency medical care.

1. Director and Deputy Directors, CBER and the Director, OCBQ, CBER.

2. Director and Deputy Directors, Center for Drug Evaluation Research (CDER).

3. Directors and Deputy Directors, Office of New Drugs, Office of Generic Drugs, and Office of Pharmaceutical Quality (CDER).

4. Director and Deputy Directors, Office of Compliance, CDER.

5. Assistant Commissioner for Operations, OO, ORA, OGROP.

- 6. Regional Food and Drug Directors and District Directors, OO, ORA, OGROP.
- 7. Director, OEIO, OO, ORA, OGROP.
- 8. Director, DIO, OEIO, OO, ORA, OGROP.

2. RE-DELEGATION

These officials may not further re-delegate these authorities.

3. EFFECTIVE DATE

The Commissioner approved this delegation, via memorandum, on May 14, 2015.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/04/2011	N/a	ORA/ORM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	05/06/2013	N/a	OGROP/ ORA/ORM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	05/14/2015	N/a	ORA/ORM	Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs
Change	06/03/2015	1.E.4. and 1.F.3.	ORA/ORM	Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs