SMG 1410.801

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

Effective Date: December 29, 2017

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized under § 801 of the Federal Food, Drug, and Cosmetic Act (the 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 Act; authorize relabeling or other compliance actions to bring articles into compliance under the Act and supervise such compliance actions:

1) Director, Office of Enforcement and Import Operations (OEIO), Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).

2) Director, Division of Enforcement (DE), OEIO, ORA, OGROP.

3) Director, Division of Food Defense Targeting (DFDT), OEIO, ORA, OGROP.

4) Director, Division of Import Operations Management (DIOM), OEIO, ORA, OGROP.

5) Director, Division of Import Program Development (DIPD), OEIO, ORA, OGROP.

6) Assistant Commissioner for Human and Animal Food Operations, Office of Human and Animal Food Operations (OHAFO), ORA, OGROP.

7) Assistant Commissioner for Medical Products and Tobacco Operations, Office of Medical Products and Tobacco Operations (OMPTO), ORA, OGROP.

8) Program Directors, Program Offices, ORA, OGROP.

9) Program Division Directors, Program Offices, ORA, OGROP.

10) Director and Deputy Directors, Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Office of Medical Products and Tobacco (OMPT).

B. The following officials are authorized, under § 536 of the 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 § 534 of the 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 § 534 of the Act (21 U.S.C. 360kk), and refuse or grant permission and time extensions to bring noncomplying products into compliance with § 534 of the Act (21 U.S.C. 360kk) in accordance with a corrective action plan approved by the:

1) Director, OEIO, ORA, OGROP.

2) Director, DIOM, OEIO, ORA, OGROP.

3) Director, DIPD, OEIO, ORA, OGROP.

4) Division Directors, Import Divisions, OEIO, ORA, OGROP.

5) Program Director, Medical Device and Radiological Health Operations, Office of Medical Devices and Radiological Health Operations (OMDRHO), OMPTO, ORA, OGROP.

6) Program Division Directors, Medical Device and Radiological Health Operations, OMDRHO, OMPTO, ORA, OGROP.

7) Director and Deputy Director, CDRH, OMPT.

8) Director and Deputy Director, Office of Compliance (OC), CDRH, OMPT.

9) Director and Deputy Director, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.

10) Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.

C. The following officials are authorized, under § 538(b) of the Act (21 U.S.C. 360oo(b)), to exempt persons from issuing a certification, as required by § 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, OEIO, ORA, OGROP.

2) Director, DIOM, OEIO, ORA, OGROP.

3) Director, DIPD, OEIO, ORA, OGROP.

4) Division Directors, Import Divisions, OEIO, ORA, OGROP.

5) Program Director, Medical Device and Radiological Health Operations, OMDRHO, OMPTO, ORA, OGROP.

6) Program Division Directors, Medical Device and Radiological Health Operations, OMDRHO, OMPTO, ORA, OGROP.

7) Director and Deputy Director, CDRH, OMPT.

8) Director and Deputy Director, OC, CDRH, OMPT.

9) Director and Deputy Director, OIR, CDRH, OMPT.

10) Director and Deputy Director, OSB, CDRH, OMPT.

D. The following officials are authorized to exercise all of the functions of the Commissioner of Food and Drugs (Commissioner) under § 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) Associate Commissioner and Deputy Associate Commissioner for Regulatory Affairs, ORA, OGROP.

2) Director, OEIO, ORA, OGROP.

3) Director, DFDT, OEIO, ORA, OGROP

4) Director, DIOM, OEIO, ORA, OGROP.

5) Director, DIPD, OEIO, ORA, OGROP.

6) Assistant Commissioner for Human and Animal Food Operations, OHAFO, ORA, OGROP.

7) Assistant Commissioner for Medical Products and Tobacco Operations, OMPTO, ORA, OGROP.

8) Program Directors, Program Offices, ORA, OGROP.

9) Program Division Directors, Program Offices, ORA, OGROP.

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

1) Program Director, Biological Products Operations, Office of Biological Products Operations (OBPO), ORA, OGROP.

2) Program Division Directors, Biological Products Operations, Office of Biological Products Operations (OBPO), ORA, OGROP.

3) Director, OEIO, ORA, OGROP.

4) Director, DIOM, OEIO, ORA, OGROP.

5) Director, DIPD, OEIO, ORA, OGROP.

6) Program Division Directors, Import Divisions, OEIO, ORA, OGROP.

7) Program Director, Medical Device and Radiological Health Operations, OMDRHO, OMPTO, ORA, OGROP.

8) Program Division Directors, Medical Device and Radiological Health Operations, OMDRHO, OMPTO, ORA, OGROP.

9) Director and Deputy Director, Center for Biologics Evaluation (CBER), OMPT.

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

11) Director and Deputy Director, CDRH, OMPT.

12) Director and Deputy Director, OC, CDRH, OMPT.

13) Director and Deputy Director, OIR, CDRH, OMPT.

14) Director and Deputy Director, OSB, CDRH, OMPT.

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

1) Program Director, Biological Products Operations, Office of Biological Products and Operations (OBPO), ORA, OGROP.

2) Program Division Directors, Biological Products Operations, OBPO, OMPTO, ORA, OGROP.

3) Director, OEIO, ORA, OGROP.

4) Director, DIOM, OEIO, ORA, OGROP.

5) Director, DIPD, OEIO, ORA, OGROP.

6) Program Division Director, Import Divisions, OEIO, ORA, OGROP.

7) Assistant Commissioner for Medical Products and Tobacco Operations, OMPTO, ORA, OGROP.

8) Program Director, Pharmaceutical Quality Operations, Office of Pharmaceutical Quality Operations (OPQO), OMPTO, ORA, OGROP.

9) Program Division Directors, Pharmaceutical Quality Operations, OPQO, OMPTO, ORA, OGROP.

10) Director and Deputy Director, CBER, OMPT.

11) Director and Deputy Director, OCBQ, CBER, OMPT.

12) Director and Deputy Director, Center for Drug Evaluation and Research (CDER), OMPT.

13) Director and Deputy Director, Office of Compliance (OC), CDER, OMPT.

14) Director and Deputy Director, Office of Generic Drugs (OGD), CDER, OMPT.

15) Director and Deputy Director, Office of New Drugs (OND), CDER, OMPT.

16) Director and Deputy Director, Office of Pharmaceutical Quality (OPQ), CDER, OMPT.

2. REDELEGATION.

These officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this delegation on December 29, 2017.

STATUS	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	N/a	1.E.4. and 1.F.3.	Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs
Revision	12/29/2017	N/a	OGROP/ ORA/OM	Scott Gottlieb, M.D., Commissioner of Food and Drugs

Back to Delegations of Authority, Volume II (1400)