SMG 1410.403

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

DETENTION OF ADULTERATED OR MISBRANDED MEDICAL DEVICES

Effective Date: July 3, 2014

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)) and in accordance with 21 CFR, Part 800, section 800.55 of 21 CFR, of medical devices that may be adulterated or misbranded: For medical devices assigned to their respective organizations:

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

2. Director and Deputy Directors, Office of Compliance, CDRH, OMPT.

3. Director and Deputy Directors, Office of In Vitro Diagnostics and Radiological Health, CDRH, OMPT.

4. Director and Deputy Directors, Office of Device Evaluation, CDRH, OMPT.

5. Director and Deputy Director, Office of Communication and Education (OCE), CDRH, OMPT.

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

7. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER, OMPT.

8. Associate Commissioner for Regulatory Affairs (ACRA) and Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), Office of the Associate Commissioner for Regulatory Affairs (OACRA), Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).

9. Regional Food and Drug Directors, Office of Operations (OO), ORA, OGROP.

10. District Directors, OO, ORA, OGROP.

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

12. Director and Deputy Directors, Office of Compliance, CDER, OMPT.

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 July 3, 2014.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/2009	N/a	OC/OO/ OM/OMP	Commissioner of Food and Drugs
Revision	02/10/2011	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	07/03/2014	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs