SMG 1410.412

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICE RECALL AUTHORITY

Effective Date: June 23, 2015

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under Section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)), delegated to the Commissioner of Food and Drugs:

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, Center for Drug Evaluation and Research (CDER), OMPT.
5. Director, Office of New Drugs, CDER, OMPT.
6. Director, Office of Generic Drugs, CDER, OMPT.
7. Director, Office of Pharmaceutical Quality, CDER, OMPT.
8. Director and Deputy Director, Office of Compliance, CDER, OMPT.
9. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), OMPT.
10. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER, OMPT.

2. RE-DELEGATION.

These officials may not further re-delegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on June 23, 2015.

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	03/23/2011	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	07/14/2014	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	06/23/2015	N/a	CDRH/OMO/ DEMO/AMB	Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs