SMG 1410.413

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

TEMPORARY SUSPENSION OF A MEDICAL DEVICE APPLICATION

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 under Section 515(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(e)), to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

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 Device Evaluation, CDRH, OMPT.

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

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

6. Director, Office of New Drugs (OND), CDER, OMPT.

7. Director, Office of Generic Drugs, (OGD), CDER, OMPT.

8. Director, Office of Pharmaceutical Quality (OPQ), CDER, OMPT.

9. Director, Office of Drug Evaluation I, II, III, and IV, OND, CDER, OMPT.

10. Director, Office of Antimicrobial Products, OND, CDER, OMPT.

11. Director, Office of Oncology Products, OND, CDER, OMPT.

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

13. Director, Office of Bioequivalence, OGD, CDER, OMPT.

14. Director, Office of Regulatory Operations, OGD, CDER, OMPT.

15. Director and Deputy Director, Office of Compliance, CDER, OMPT.

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

17. 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