SMG 1410.415

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – MEDICAL DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES POSTMARKET SURVEILLANCE

Effective Date: November 13, 2018

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The officials listed below, for medical devices assigned to their respective organization, are authorized under Section 522(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601(a)(1)(A)) to require a manufacturer to conduct postmarket surveillance for any Class II or Class III device (including any device that is or contains a drug or biologic), the failure of which would be reasonably likely to have serious adverse health consequences, that is expected to have significant use in pediatric populations, or that which is intended to be implanted in the human body for more than 1 year, or a life supporting or life sustaining device used outside a user facility:

1. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), Office of Medical Products and Tobacco (OMPT).

2. Director and Deputy Director, Office of Blood Research and Review (OBRR), CBER, OMPT.

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

4. Director and Deputy Director, Office of Tissues and Advanced Therapies (OTAT), CBER, OMPT.

5. Director and Deputy Director, Office of Vaccines Research and Review (OVRR), CBER, OMPT.

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

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

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

9. Director, Office of Bioequivalence (OB), OGD, CDER, OMPT.

10. Director, Office of Regulatory Operations (ORO), OGD, CDER, OMPT.

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

12. Director, Office of Antimicrobial Products (OAP), OND, CDER, OMPT.

13. Directors, Office of Drug Evaluation I (ODE I), II (ODE II), III (ODE III), and IV (ODE IV), OND, CDER, OMPT.

14. Director, Office of Hematology and Oncology Products (OHOP), OND, CDER, OMPT.

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

16. Director and Deputy Director, Office of Surveillance and Epidemiology, (OSE), CDER, OMPT.

17. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT.

18. Director, Deputy Directors, and Associate Directors, Office of Compliance (OC), CDRH, OMPT.

19. Director and Deputy Director, Division of Bioresearch Monitoring (DBM), OC, CDRH, OMPT.

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

21. Director, Deputy Directors, and Associate Directors, Office of Device Evaluation (ODE), CDRH, OMPT.

22. Clinical Trials Director, Clinical Trials Staff (CTS), ODE, CDRH, OMPT.

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

24. Director, Deputy Directors and Associate Directors, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.

25. Director and Deputy Director, Division of Epidemiology (DEPI), OSB, CDRH, OMPT.

26. Director and Deputy Director, Division of Postmarket Surveillance (DPS), OSB, CDRH, OMPT.

27. Director and Deputy Directors, Office of Science and Engineering Laboratories (OSEL), CDRH, OMPT.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this Delegation, via memorandum, on November 13, 2018.

STATUS	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	07/14/2015	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 M. Ostroff, M.D. Acting Commissioner of Food and Drugs
Revision	11/13/2018	N/a	OMPT/CDRH/ OMO/DEMO	Scott Gottlieb, M.D. Commissioner of Food and Drug

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