SMG 1410.416

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – MEDICAL DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICE REPORTING PROCEDURES

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 to approve electronic reporting under 21 CFR Section 803.14:

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

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

3. Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.

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

5. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.

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

7. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.

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

9. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

B. The officials listed below, for medical devices assigned to their respective organization, are authorized to request the submission of additional information under 21 CFR Section 803.15:

1. Director and Deputy Directors, CDRH, OMPT.

2. Director, Deputy Directors, and Associate Directors, OC, CDRH, OMPT.

3. Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.

4. Director, Deputy Directors, and Associate Directors, ODE, CDRH, OMPT.

5. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.

6. Director, Deputy Directors, and Associate Directors, OIR, CDRH, OMPT.

7. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.

8. Director, Deputy Directors, and Associate Directors, OSB, CDRH, OMPT.

9. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

C. The officials listed below, for medical devices assigned to their respective organization, are authorized to grant or revoke exemptions and variances from reporting requirements under 21 CFR Section 803.19:

1. Director and Deputy Directors, CDRH, OMPT.

2. Director, Deputy Directors, and Associate Directors, OC, CDRH, OMPT.

3. Division Directors, Deputy Division Directors, Associate Division Directors, OC, CDRH, OMPT.

4. Director, Deputy Directors, and Associate Directors, ODE, CDRH, OMPT.

5. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.

6. Director, Deputy Directors, and Associate Directors, OIR, CDRH, OMPT.

7. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.

8. Director, Deputy Directors, and Associate Directors, OSB, CDRH, OMPT.

9. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, 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, 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	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	03/22/2012	N/a	CDRH/OMO	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	11/22/2013	N/a	CDRH/OMO/ DEMO/AMB	Walter S. Harris, M.B.A. Deputy Commissioner for Operations & Chief Operating Officer
Revision	11/13/2018	N/a	OMPT/CDRH/ OM/DWM	Scott Gottlieb, M.D. Commissioner of Food and Drug

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