SMG 1410.414

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – MEDICAL DEVICES AND RADIOLOGICAL HEALTH

APPROVAL, DISAPPROVAL, OR WITHDRAWAL OF APPROVAL OF APPLICATIONS AND ENTERING INTO AGREEMENTS FOR INVESTIGATIONAL DEVICE EXEMPTIONS

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, disapprove, or withdraw approval of applications for investigational device exemptions submitted under Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360j(g)):

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 Tissues and Advanced Therapies (OTAT), CBER, OMPT.

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

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

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

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

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

9. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, OC, CDRH, OMPT.

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

11. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, ODE, CDRH, OMPT.

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

13. Chief, Investigational Device Exemption Section (IDE), CTS, ODE, CDRH, OMPT.

14. Director, Program Operations Staff (POS), ODE, CDRH, OMPT.

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

16. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, OIR, CDRH, OMPT.

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

18. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, OSB, CDRH, OMPT.

B. The officials listed below, for medical devices assigned to their respective organization, are authorized to enter into written agreements concerning investigational device exemption protocols under Section 520(g)(7) of the Act (21 U.S.C. 360j(g)(7)):

1. Director and Deputy Director, CBER, OMPT.

2. Director and Deputy Director, OBRR, CBER, OMPT.

3. Director and Deputy Director, OTAT, CBER, OMPT.

4. Director and Deputy Director, OVRR, CBER, OMPT.

5. Director and Deputy Directors, CDER, OMPT.

6. Director and Deputy Directors, OND, CDER, OMPT.

7. Director and Deputy Directors, CDRH, OMPT.

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

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

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

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

12. Clinical Trials Director, CTS, ODE, CDRH, OMPT.

13. Chief, IDE, CTS, ODE, CDRH, OMPT.

14. Director, POS, ODE, CDRH, OMPT.

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

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

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

18. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, 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	04/01/2011	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

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Revision	11/13/2018	N/a	OMPT/CDRH/ OM/DWM	Scott Gottlieb, M.D. Commissioner of Food and Drug

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