SMG 1410.26

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – GENERAL REDELEGATION OF AUTHORITY

RESEARCH, INVESTIGATION, AND TESTING PROGRAMS AND HEALTH PROMOTION PROGRAMS

Effective Date: November 13, 2018
Change: December 19, 2018

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The officials listed below are authorized under Sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241, 242l, 243, 300u, 300u-1, 300u-2, 300u-3) to establish research, investigation, and testing programs and health information and health promotion programs, which relate to their assigned functions and to approve grants for conducting such programs:

1. Director, National Center for Toxicological Research (NCTR), Office of the Chief Scientist (OCS), Office of the Commissioner (OC).

2. Associate Director for Research, NCTR, OCS, OC.

3. Associate Director for Management, NCTR, OCS, OC.

4. Associate Commissioner for External Affairs, Office of External Affairs (OEA), OC.

5. Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), Office of Foods and Veterinary Medicine (OFVM).

6. Director and Deputy Director, International Affairs Staff (IAS), CFSAN, OFVM.

7. International Policy Managers, IAS, CFSAN, OFVM.

8. Director and Deputy Director, Center for Veterinary Medicine (CVM), OFVM.

9. Associate Commissioner for International Programs, Office of International Programs (OIP), Office of Global Regulatory Operations and Policy (OGROP).

10. Associate Director for Technical Cooperation and Capacity Building, OIP, OGROP.

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

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

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

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

15. Director and Deputy Director, Office of Research and Standards (ORS), OGD, CDER, OMPT.

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

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

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

19. Director and Deputy Director, Center for Tobacco Products (CTP), OMPT.

20. Associate Commissioner for Special Medical Programs, Office of Special Medical Programs (OSMP), OMPT.

21. Director, Office of Orphan Products Development (OOPD), OSMP, OMPT.

B. The official listed below is authorized to establish an electronic product radiation control program and to approve grants for conducting the program under Section 532 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ii):

1. Director and Deputy Directors, CDRH, OMPT.

C. The officials listed below are authorized to sign and issue all notices of grant awards and amendments thereto, and sign and issue notices of suspension and termination thereof, for grants approved under paragraphs A and B of this Delegation of Authority:

1. Chief Operating Officer, Office of Operations (OO).

2. Director, Office of Acquisitions and Grants Services (OAGS), Office of Finance Budget and Acquisition (OFBA), OO.

3. Director, Division of Contracts and Grants Management (DCGM), OAGS, OFBA, OO.

4. Chief Grants Management Officer and Grants Management Officer, DCGM, OAGS, OFBA, OO.

D. The official listed below is authorized under Sections 301 of the PHS Act (42 U.S.C. 241), as amended by Public Law 95-622, to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of the Center that are not required to support Center research programs:

1. Director, NCTR, OCS, OC.

E. The officials listed below are authorized to issue Certificates of Confidentiality under Section 301 of the PHS Act (42 U.S.C. 241):

1. Deputy Directors, CFSAN, OFVM.

2. Director, Senior Science Advisor Staff (SSAS), CFSAN, OFVM.

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

4. Director, Division of Inspections and Surveillance (DIS), CBER, OMPT.

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

6. Director and Deputy Director, Division of Scientific Investigation (DSI), OC, CDER, OMPT.

7. Director and Deputy Directors, CDRH, OMPT.

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

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

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

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

2. REDELEGATION.

A. These officials may not further redelegate these authorities with the exception of the authorities in Paragraph 1.C.

B. The Chief Operating Officer may further redelegate the authorities in Paragraph 1.C.

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	06/08/2010	N/a	OC/OA/OM/OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	11/09/2011	N/a	OO/OM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	11/13/2018	N/a	OO/OFBA/OB	Scott Gottlieb, M.D. Commissioner of Food and Drug
Change	12/19/2018	Para. 1.E.1,2	OO/OFBA/OB	Scott Gottlieb, M.D. Commissioner of Food and Drug

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