

**FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY**

**REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY**

**CERTIFICATION OF TRUE COPIES AND USE OF DEPARTMENT SEAL**

Effective Date: 04/22/2015

**1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.**

A. The following officials are authorized to certify true copies of, or extracts from, any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

1. Deputy Commissioner for Operations and Chief Operating Officer, Office of Operations (OO); Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of Policy, Planning, Legislation and Analysis (OPPLA); Deputy Commissioner for Foods and Veterinary Medicine, Office of Food and Veterinary Medicine (OFVM); Deputy Commissioner for Global Regulatory Operations and Policy, Office of Global Regulatory Operations and Policy (OGROP); Deputy Commissioner for Medical Products and Tobacco (OMPT); Deputy Commissioner for Science and Public Health and Chief Scientist; and Chief of Staff.
2. Associate Commissioners and Assistant Commissioners, Chief Counsel and Deputy Chief Counsel, Office of the Commissioner (OC).
3. Director, Office of the Executive Secretariat (OES), OC.
4. Associate Commissioner and Assistant Commissioner, Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).
5. Director, Office of Criminal Investigations (OCI), ORA, OGROP.
6. Director and Deputy Director, Office of Enforcement and Import Operations (OEIO), Office of Operations (OO), ORA, OGROP.
7. Director and Deputy Director, Office of Policy and Risk Management (OPRM), ORA, OGROP.
8. Director, Food and Feed Policy Staff, OPRM, ORA, OGROP

9. Director, Medical Products and Tobacco Policy Staff, OPRM, ORA, OGROP.
10. Director, Risk Management Staff, OPRM, ORA, OGROP.
11. Director and Deputy Director, Office of Food and Feed Operations (OFFO), OO, ORA, OGROP.
12. Director and Deputy Director, Office of Medical Products and Tobacco Operations (OMPTO), OO, ORA, OGROP.
13. Director and Deputy Director, Office of Resource Management (ORM), ORA, OGROP.
14. Director, Division of Management Operations, ORM, ORA, OGROP.
15. Regional Food and Drug Directors, OO, ORA, OGROP.
16. District Directors, Regional Field Offices, OO, ORA, OGROP.
17. Director, Northeast Regional Laboratory, Northeast Region, OO, ORA, OGROP.
18. Director, Southeast Regional Laboratory, Southeast Region, OO, ORA, OGROP.
19. Director, Pacific Regional Laboratory, Northwest, Pacific Region, OO, ORA, OGROP.
20. Director, Pacific Regional Laboratory, Southwest, Pacific Region, OO, ORA, OGROP.
21. Director, National Forensic Chemistry Center, Central Region, OO, ORA, OGROP.
22. Director, Arkansas Regional Laboratory, Southwest Region, OO, ORA, OGROP.
23. Director, Winchester Engineering Analytical Center, Northeast Region, OO, ORA, OGROP.
24. Chief Information Officer, Office of Information Management and Technology (OIMT), OO.
25. Director, Freedom of Information Staff (FOIS), OES, OC.

26. Director, Dockets Management Staff (DMS), OES, OC.
27. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), Office of Medical Products and Tobacco (OMPT).
28. Director and Deputy Director, Office of Management (OM), CBER, OMPT.
29. Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT.
30. Director and Deputy Director, Office of Communication, Outreach and Development, CBER, OMPT.
31. Director and Branch Chiefs, Division of Case Management, OCBQ, CBER, OMPT; and Consumer Safety Officers, OCBQ, CBER, OMPT.
32. Freedom of Information Officers, CBER, OMPT.
33. Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), Office of Foods and Veterinary Medicine (OFVM).
34. Director, Office of Regulations, Policy and Social Sciences, CFSAN, OFVM.
35. Associate Director, Office of Management (OM), CFSAN, OFVM.
36. Director, Office of Cosmetics and Colors, CFSAN, OFVM.
37. Director, Office of Food Safety, CFSAN, OFVM.
38. Director, Office of Nutrition, Labeling, and Dietary Supplements, CFSAN, OFVM.
39. Director, Office of Regulatory Science, CFSAN, OFVM.
40. Director, Office of Compliance, CFSAN, OFVM.
41. Director and Deputy Director, Office of Food Additive Safety, CFSAN, OFVM.
42. Director, Office of Applied Research and Safety Assessment, CFSAN, OFVM.
43. Freedom of Information Officers, CFSAN, OFVM.
44. Director, Deputy Directors, and Senior Associate Director, Center for Devices and Radiological Health (CDRH), OMPT.

45. Associate Director for Management, Office of the Center Director, CDRH, OMPT.
46. Director and Deputy Directors, Office of Compliance (OC), CDRH, OMPT.
47. For medical devices assigned to their respective divisions, Division Directors, OC, CDRH, OMPT.
48. Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, OMPT.
49. For medical devices assigned to their respective divisions, Division Directors, ODE, CDRH, OMPT.
50. Director and Deputy Directors, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.
51. Director, Office of Management Operations (OMO), CDRH, OMPT.
52. Freedom of Information Officers, CDRH, OMPT.
53. Director and Deputy Director, Center for Tobacco Products (CTP), (OMPT).
54. Director and Deputy Director, Office of Management (OM), CTP, OMPT.
55. Director and Deputy Director, Office of Compliance and Enforcement, CTP, OMPT.
56. Director and Deputy Director, Office of Regulations, CTP, OMPT.
57. Director, Deputy Director for Research, and Deputy Director for Regulatory Science and Management, Office of Science, CTP, OMPT.
58. Freedom of Information Officers, CTP, OMPT.
59. Director and Deputy Directors, Center for Veterinary Medicine, CVM, OFVM.
60. Associate Director for Policy and Communications, Office of Center Director, CVM, OFVM.
61. Director and Deputy Director, Office of Surveillance and Compliance (OSC), CVM, OFVM.
62. Director, Division of Compliance, OSC, CVM, OFVM.
63. Freedom of Information Officers, CVM, OFVM.

64. Director, Deputy Director and Associate Directors for Research, Management, Executive Programs and Services, and Regulatory Activities, respectively, National Center for Toxicological Research (NCTR), Office of the Chief Scientist (OCS), OC.
65. Associate Director for Management, Office of Management (OM), NCTR, OCS, OC.
66. Freedom of Information Officers, NCTR, OCS, OC.
67. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), OMPT.
68. Directors and Deputy Directors, Office of New Drugs (OND), Office of Generic Drugs (OGD) Office of Pharmaceutical Quality (OPQ), Office of Translational Sciences (OTS), Office of Counter-Terrorism and Emergency Coordination (OCTEC), Office of Executive Programs (OEP), and Office of Surveillance and Epidemiology (OSE); Associate Director for Policy, Office of Regulatory Policy (ORP); and Associate Director for Medical Policy, Office of Medical Policy (OMP), CDER, OMPT
69. Director and Deputy Director, Office of Management (OM), CDER, OMPT.
70. Director and Deputy Directors, Office of Compliance (OC), CDER, OMPT.
71. Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, and IV, Office of Antimicrobial Products, and Office of Hematology and Oncology Products, OND, CDER, OMPT.
72. Directors and Deputy Directors of the Office of Testing and Research, Office of New Drug Products, and Office of Biotechnology Products, OPQ; Office of Biostatistics and Office of Clinical Pharmacology, OTS; and Office of Business Informatics, OBI, CDER, OMPT.
73. Director, Division of Information Disclosure Policy, ORP, CDER, OMPT.
74. Directors and Deputy Directors, Office of Drug Security, Integrity and Recalls, Office of Manufacturing and Product Quality, Office of Scientific Investigations, and Office of Unapproved Drugs and Labeling Compliance, OC, CDER, OMPT.
75. Freedom of Information Officers, CDER, OMPT.

B. The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

1. Deputy Commissioner for Operations and Chief Operating Officer, Office of Operations (OO); Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of Policy, Planning, Legislation and Analysis (OPPLA); Deputy Commissioner for Foods and Veterinary Medicine, Office of Foods and Veterinary Medicine (OFVM); Deputy Commissioner for Global Regulatory Operations and Policy, Office of Global Regulatory Operations and Policy (OGROP); Deputy Commissioner for Medical Products and Tobacco, Office of Medical Products and Tobacco (OMPT); Deputy Commissioner for Science and Public Health and Chief Scientist; and Chief of Staff.
  2. Associate Commissioners, Assistant Commissioners, Chief Counsel and Deputy Chief Counsel.
  3. Director, Office of Executive Secretariat, OC.
  4. Director and Deputy Director, CBER, OMPT; Director and Deputy Directors, CFSAN, OFVM; Director, Deputy Directors, and Senior Associate Director, CDRH, OMPT; Director, Executive Director, and Senior Advisor for Science Policy, CVM, OFVM; Director and Deputy Directors, CDER, OMPT; Director, NCTR, OCS, OC; Associate Directors, Offices of Regulatory Compliance and Risk Management, Management, NCTR, OCS, OC; and Director and Deputy Director, CTP, OMPT.
  5. Director, OBS, OO; Director, OM, CBER, OMPT; Director, OM, CDER, OMPT; Director, OM, CFSAN, OFVM; Director, OMO, CDRH, OMPT.
  6. Director, OM, CTP, OMPT.
  7. Associate Director for Management, OM, CVM, OFVM.
  8. Executive Officer, OM, NCTR, OCS, OC.
  9. Freedom of Information Officers.
- C. Chief, Regulations Editorial Section (RES), Regulations Policy and Management Staff (RPMS), Office of Policy (OPPLA), and his or her alternates are authorized to certify true copies of Federal Register documents.

## **2. RE-DELEGATION STATEMENTS.**

- A. The following Officials may further re-delegate the authorities under paragraphs 1.A. and 1.B. of this delegation:

1. Deputy Commissioner for Operations and Chief Operating Officer, Office of Operations (OO); Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of Policy, Planning, Legislation and Analysis (OPPLA); Deputy Commissioner for Foods and Veterinary Medicine, Office of Foods and Veterinary Medicine (OFVM); Deputy Commissioner for Global Regulatory Operations and Policy, Office of Global Regulatory Operations and Policy (OGROP); Deputy Commissioner for Medical Products and Tobacco, Office of Medical Products and Tobacco (OMPT); Deputy Commissioner for Science and Public Health and Chief Scientist; and Chief of Staff; Associate and Assistant Commissioners; Chief Counsel and Deputy Chief Counsel.
2. Directors and Deputy Directors for OES,OC; CBER, OMPT; CFSAN, OFVM; CDRH, OMPT; CDER, OMPT; CTP, OMPT; CVM, OFVM; and NCTR, OCS, OC.
3. Center Associate Directors for Management; CDER, OMPT; Director, ORM, ORA, OGROP; Director, OBS, OO.

B. The other Officials delegated authority by this Section may not further re-delegate it.

C. Under paragraph 1.C., Chief, RES, RPMS, OP, OPPLA may designate alternates, as required.

### 3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on April 22, 2015.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/20/2011	N/a	FDA/OC/OA/OM/OMP	Margaret A. Hamburg M.D., Commissioner of Food and Drugs
Revision	04/22/2015	N/a	FDA/OC/OES	Stephen Ostroff M.D., Acting Commissioner of Food and Drugs