

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

**REGULATORY – GENERAL REDELEGATION OF AUTHORITY**

**ISSUANCE OF REPORTS OF MINOR VIOLATIONS**

Effective Date: October 29, 2018

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

A. The officials listed below are authorized to perform all the functions of the Commissioner of Food and Drugs (the Commissioner) regarding the issuance of written notices or warnings under Section 309 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 336):

- 1) Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), Office of Foods and Veterinary Medicine (OFVM).
- 2) Director and Deputy Director, Office of Compliance (OC), CFSAN, OFVM.
- 3) Director, Division of Enforcement (DE), OC, CFSAN, OFVM.
- 4) Director, Division of Field Programs and Guidance (DFPG), OC, CFSAN, OFVM.
- 5) Director, Office of Regulations and Policy (ORP), CFSAN, OFVM.
- 6) Director and Deputy Directors, Center for Veterinary Medicine (CVM), OFVM.
- 7) Senior Advisor for Science Policy, CVM, OFVM.
- 8) Director and Deputy Director, Office of Compliance (OC), OSC, CVM, OFVM.
- 9) Director and Deputy Director, Office of Surveillance (OS), OSC, CVM, OFVM.
- 10) Director and Deputy Director, Office of Surveillance and Compliance (OSC), CVM, OFVM.
- 11) Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).
- 12) Director, Office of Enforcement and Import Operations (OEIO), ORA, OGROP.

- 13) Director, Division of Enforcement (DE), OEIO, ORA, OGROP.
- 14) Director, Division of Import Operations and Management (DIOM), OEIO, ORA, OGROP.
- 15) Assistant Commissioner for Human and Animal Food Operations, Office of Human and Animal Food Operations (OHAFO), ORA, OGROP.
- 16) Director, Office of Human and Animal Food Operations East (OHAFOE), OHAFO, ORA, OGROP.
- 17) Director, Division of Human and Animal Food Operations East I, (DHAFOEI), OHAFOE, OHAFO, ORA, OGROP.
- 18) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOEI, OHAFOE, OHAFO, ORA, OGROP.
- 19) Director, Division of Human and Animal Food Operations East II (DHAFOEII), OHAFOE, OHAFO, ORA, OGROP.
- 20) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOEII, OHAFOE, OHAFO, ORA, OGROP.
- 21) Director, Division of Human and Animal Food Operations East III (DHAFOEIII), OHAFOE, OHAFO, ORA, OGROP.
- 22) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOEIII, OHAFOE, OHAFO, ORA, OGROP.
- 23) Director, Division of Human and Animal Food Operations East IV (DHAFOEIV), OHAFOE, OHAFO, ORA, OGROP.
- 24) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOEIV, OHAFOE, OHAFO, ORA, OGROP.
- 25) Director, Division of Human and Animal Food Operations East V (DHAFOEV), OHAFOE, OHAFO, ORA, OGROP.
- 26) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOEV, OHAFOE, OHAFO, ORA, OGROP.
- 27) Director, Division of Human and Animal Food Operations East VI (DHAFOEVI), OHAFOE, OHAFO, ORA, OGROP.
- 28) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOEVI, OHAFOE, OHAFO, ORA, OGROP.

- 29) Director, Office of Human and Animal Food Operations West (OHAFOW), OHAFO, ORA, OGROP.
- 30) Director, Division of Domestic Human and Animal Food Operations (DDHAFO), OHAFOW, OHAFO, ORA, OGROP.
- 31) Director, Division of Human and Animal Food Operations West I, (DHAFOWI), OHAFOW, OHAFO, ORA, OGROP.
- 32) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOWI, OHAFOE, OHAFO, ORA, OGROP.
- 33) Director, Division of Human and Animal Food Operations West II, (DHAFOVII), OHAFOW, OHAFO, ORA, OGROP.
- 34) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOVII, OHAFOE, OHAFO, ORA, OGROP.
- 35) Director, Division of Human and Animal Food Operations West III, (DHAFOVIII), OHAFOW, OHAFO, ORA, OGROP.
- 36) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOVIII, OHAFOE, OHAFO, ORA, OGROP.
- 37) Director, Division of Human and Animal Food Operations West IV, (DHAFOIV), OHAFOW, OHAFO, ORA, OGROP.
- 38) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOIV, OHAFOE, OHAFO, ORA, OGROP.
- 39) Director, Division of Human and Animal Food Operations West V, (DHAFOV), OHAFOW, OHAFO, ORA, OGROP.
- 40) Chief, Human and Animal Food Compliance Branch (HAFCB), DHAFOV, OHAFOE, OHAFO, ORA, OGROP.
- 41) Director, Division of Human and Animal Food Operations West VI, (DHAFOVI), OHAFOW, OHAFO, ORA, OGROP.
- 42) Chief, Human and Animal Food Compliance Branch (HAFCB), (DHAFOVI), OHAFOE, OHAFO, ORA, OGROP.
- 43) Director, Office of State Cooperative Programs (OSCP), OHAFO, ORA, OGROP.

- 44) Assistant Commissioner for Medical Products and Tobacco Operations, Office of Medical Products and Tobacco Operations (OMPTO), ORA, OGROP.
- 45) Director, Office of Bioresearch Monitoring Operations (OBIMO), OMPTO, ORA, OGROP.
- 46) Director, Division of Bioresearch Monitoring Operations I (DBIMOI), OBIMO, OMPTO, ORA, OGROP.
- 47) Director, Division of Bioresearch Monitoring Operations II (DBIMOI), OBIMO, OMPTO, ORA, OGROP.
- 48) Director, Office of Biological Products Operations (OBPO), OMPTO, ORA, OGROP.
- 49) Director, Division of Biological Products Operations I (DBPOI), OBPO, OMPTO, ORA, OGROP.
- 50) Chief, Biological Products Compliance Branch (BPCB), DBPOI, OBPO, OMPTO, ORA, OGROP.
- 51) Director, Division of Biological Products Operations II (DBPOII), OBPO, OMPTO, ORA, OGROP.
- 52) Chief, Biological Products Compliance Branch (BPCB), DBPOII, OBPO, OMPTO, ORA, OGROP.
- 53) Director, Office of Medical Devices and Radiological Health Operations (OMDRHO), OMPTO, ORA, OGROP.
- 54) Director, Division of Medical Devices and Radiological Health Operations I (DMDRHOI), OMDRHO, OMPTO, ORA, OGROP.
- 55) Chief, Medical Devices and Radiological Health Compliance Branch (MDRHCB), DMDRHOI, OMDRHO, OMPTO, ORA, OGROP.
- 56) Director, Division of Medical Devices and Radiological Health Operations II (DMDRHOII), OMDRHO, OMPTO, ORA, OGROP.
- 57) Chief, Medical Devices and Radiological Health Compliance Branch (MDRHCB), DMDRHOII, OMDRHO, OMPTO, ORA, OGROP.
- 58) Director, Division of Medical Devices and Radiological Health Operations III (DMDRHOIII), OMDRHO, OMPTO, ORA, OGROP.

- 59) Chief, Medical Devices and Radiological Health Compliance Branch (MDRHCB), DMDRHOIII, OMDRHO, OMPTO, ORA, OGROP.
- 60) Director, Office of Pharmaceutical Quality Operations (OPQO), OMPTO, ORA, OGROP.
- 61) Director, Division of Foreign Pharmaceutical Quality Inspections (DFPQI), OPQO, OMPTO, ORA, OGROP.
- 62) Director, Division of Pharmaceutical Quality Operations I (DPQOI), OPQO, OMPTO, ORA, OGROP.
- 63) Chief, Pharmaceutical Quality Compliance Branch (PQCB), DPQI,OPQO, OMPTO, ORA, OGROP.
- 64) Director, Division of Pharmaceutical Quality Operations II (DPQOII), OPQO, OMPTO, ORA, OGROP.
- 65) Chief, Pharmaceutical Quality Compliance Branch (PQCB), DPQII, OPQO, OMPTO, ORA, OGROP.
- 66) Director, Division of Pharmaceutical Quality Operations III (DPQOIII), OPQO, OMPTO, ORA, OGROP.
- 67) Chief, Pharmaceutical Quality Compliance Branch (PQCB), DPQIII,OPQO, OMPTO, ORA, OGROP.
- 68) Director, Division of Pharmaceutical Quality Operations IV (DPQOIV), OPQO, OMPTO, ORA, OGROP.
- 69) Chief, Pharmaceutical Quality Compliance Branch (PQCB), DPQIV, OPQO, OMPTO, ORA, OGROP.
- 70) Director, Office of Regulatory Science (ORS), ORA, OGROP.
- 71) Associate Director for Laboratory Operations, Office of Food and Feed Laboratory Operations (OFFLO), ORS, ORA, OGROP.
- 72) Director, Arkansas Laboratory (ARKL), OFFLO, ORS, ORA, OGROP.
- 73) Director, Denver Laboratory (DENL), OFFLO, ORS, ORA, OGROP.
- 74) Director, Kansas City Laboratory (KCL), OFFLO, ORS, ORA, OGROP.
- 75) Director, Northeast Food and Feed Laboratory (NFFL), OFFLO, ORS, ORA, OGROP.

- 76) Director, Pacific Northwest Laboratory (PNL), OFFLO, ORS, ORA, OGROP.
- 77) Director, Pacific Southwest Food and Feed Laboratory (PSFFL), OFFLO, ORS, ORA, OGROP.
- 78) Director, San Francisco Laboratory (SANFL), OFFLO, ORS, ORA, OGROP.
- 79) Director, Southeast Food and Feed Laboratory (SFFL), OFFLO, ORS, ORA, OGROP.
- 80) Associate Director for Laboratory Operations, Office of Medical Products, Tobacco, and Specialty Laboratory Operations (OMPTSLO), ORS, ORA, OGROP.
- 81) Director, Detroit Laboratory (DETL), OMPTSLO, ORS, ORA, OGROP.
- 82) Director, Forensic Chemistry Center (FCC), OMPTSLO, ORS, ORA, OGROP.
- 83) Director, Northeast Medical Products Laboratory (NMPL), OMPTSLO, ORS, ORA, OGROP.
- 84) Director, Philadelphia Laboratory (PHIL), OMPTSLO, ORS, ORA, OGROP.
- 85) Director, Pacific Southwest Medical Products Laboratory (PSMPL), OMPTSLO, ORS, ORA, OGROP.
- 86) Director, San Juan Laboratory (SJM), OMPTSLO, ORS, ORA, OGROP.
- 87) Director, Southeast Tobacco Laboratory (STL), OMPTSLO, ORS, ORA, OGROP.
- 88) Director, Winchester Engineering and Analytical Center (WEAC), OMPTSLO, ORS, ORA, OGROP.
- 89) Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), Office of Medical Products and Tobacco (OMPT).
- 90) Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT.
- 91) Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), OMPT.
- 92) Director and Deputy Directors, Office of Compliance (OC), CDER, OMPT.

- 93) Director and Deputy Director, Office of Generic Drugs (OGD), CDER, OMPT.
- 94) Director, Office of Medical Policy (OMP), CDER, OMPT.
- 95) Director, Office of Prescription Drug Promotion (OPDP), OMP, CDER, OMPT.
- 96) Director and Deputy Directors, Office of New Drugs (OND), CDER, OMPT.
- 97) Director and Deputy Director, Office of Pharmaceutical Quality (OPQ), CDER, OMPT.
- 98) Director, Office of Regulatory Policy (ORP), CDER, OMPT.
- 99) Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT.
- 100) Director, Deputy Directors, and Associate Directors, Office of Compliance (OC), CDRH, OMPT.
- 101) Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.
- 102) Director, Deputy Directors, and Associate Directors, Office of Device Evaluation (ODE), CDRH, OMPT.
- 103) Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.
- 104) Director, Deputy Directors, and Associate Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.
- 105) Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.
- 106) Director, Deputy Directors, and Associate Directors, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.
- 107) Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.
- 108) Director and Deputy Director, Center for Tobacco Products (CTP), OMPT.
- 109) Director and Deputy Directors, Office of Compliance and Enforcement (OCE), CTP, OMPT.

B. The officials listed below, for medical devices assigned to their organization, are authorized to perform all the functions of the Commissioner regarding the issuance of written notices or warnings under Section 539(d) of the Act (21 U.S.C. 360pp(d)):

- 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 are authorized to perform all the functions of the Commissioner regarding the issuance of written notices or warnings under Section 539(d) of the Act (21 U.S.C. 360pp(d)) when such functions relate to:

- Assemblers of diagnostic x-ray system, as defined in 21 CFR 1020.30(b), and
  - Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in 21 CFR 1040.20(b)
- 1) Assistant Commissioner for Medical Products and Tobacco Operations, OMPTO, ORA, OGROP.
  - 2) Director, Office of Medical Device and Radiological Health Operations (OMDRHO), OMPTO, ORA, OGROP.
  - 3) Director, Division of Medical Devices and Radiological Health Operations I (DMDRHOI), OMDRHO, OMPTO, ORA, OGROP.



- 4) Director, Division of Medical Devices and Radiological Health Operations II (DMDRHOII), OMDRHO, OMPTO, ORA, OGROP.
- 5) Director, Division of Medical Devices and Radiological Health Operations III (DMDRHOIII), OMDRHO, OMPTO, ORA, OGROP.

**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 October 29, 2018.

<b>STATUS</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	04/10/2009	N/a	OC/OA/ OM/OMP	Margaret A. Hamburg, M.D.. Commissioner of Food and Drugs
Revision	06/04/2010	N/a	OC/OA/ OM/OMP	Margaret A. Hamburg, M.D.. Commissioner of Food and Drugs
Revision	04/09/2015	N/a	OO/OHR/ MASS	Stephen M. Ostroff, M.D. Acting Commissioner of Food and Drugs
Revision	10/29/2018	N/a	OGROP/ORO/ OM	Scott Gottlieb, M.D. Commissioner of Food and Drugs

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