

**FDA Staff Manual Guides, Volume II – Delegations of Authority**

**Regulatory – General Redelelegation of Authority**

**Disclosure of Non-Public Information to Foreign Government Officials  
or Receipt of Non-Public Information from Foreign Government Officials**

Effective Date: 9 June 2020

**1. Authority Delegated and To Whom Delegated.**

A. The officials listed below are delegated the authority to disclose official records and information to foreign government officials under 21 CFR 20.89(c), and 20.89(d). Such officials may disclose such information directly or may authorize such disclosure and designate FDA staff to transmit such information to foreign government officials on their behalf whether for an individual disclosure or a series of disclosures at the discretion of the official. The officials listed below are also delegated the authority to authorize receiving of official records and information from foreign government officials under 21 CFR 20.89(d). Such officials may disclose or receive such information directly or may authorize such disclosure or receiving and designate FDA staff to disclose or receive such information from foreign government officials on their behalf whether for an individual disclosure or receiving, or a series of disclosures or receivings, at the discretion of the official:

- (1) Office of the Commissioner (OC) Principal Deputy Commissioner.
- (2) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.
- (3) CBER/Office of Compliance and Biologics Quality (OCBQ) Director and Deputy Directors.
- (4) CBER/Office of Communication, Outreach, and Development (OCOD) Director and Deputy Director.
- (5) CBER Senior Advisor for International Affairs.
- (6) Center for Drug Evaluation and Research (CDER) Director, Deputy Directors, and Associate Director for Strategic Initiatives.
- (7) CDER/Office of Compliance (OC) Director and Deputy Directors.
- (8) CDER/OC/Office of Drug Security, Integrity, and Response (ODSIR) Director and Deputy Director.
- (9) CDER/OC/Office of Manufacturing Quality (OMQ) Director and Deputy Directors.
- (10) CDER/OC/Office of Scientific Investigations (OSI) Director and Deputy Director.

- (11) CDER/OC/Office of Unapproved Drugs and Labeling Compliance (OUDLC) Director and Deputy Director.
- (12) CDER/Office of Communications (OCOMM) Director and Deputy Director.
- (13) CDER/Office of Generic Drugs (OGD) Director and Deputy Director.
- (14) CDER/OGD/Office of Bioequivalence (OB) Director and Deputy Director.
- (15) CDER/OGD/Office of Generic Drug Policy (OGDP) Director and Deputy Director.
- (16) CDER/OGD/Office of Regulatory Operations (ORO) Director and Deputy Director.
- (17) CDER/OGD/Office of Research and Standards (ORS) Director and Deputy Director.
- (18) CDER/Office of Medical Policy (OMP) Director and Deputy Director.
- (19) CDER/OMP/Office of Medical Policy Initiative (OMPI) Director and Deputy Director.
- (20) CDER/OMP/Office of Prescription Drug Promotion (OPDP) Director and Deputy Director.
- (21) CDER/Office of New Drugs (OND) Director and Deputy Director.
- (22) CDER/OND/Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN) Director and Deputy Directors.
- (23) CDER/OND/Office of Infectious Diseases (OID) Director and Deputy Director.
- (24) CDER/OND/Office of Immunology and Inflammation (OII) Directors and Deputy Directors.
- (25) CDER/OND/Office of Neuroscience (ON) Directors and Deputy Directors.
- (26) CDER/OND/Office of Oncological Diseases (OOD) Director and Deputy Director.
- (27) CDER/OND/Office of Rare Diseases, Pediatrics, Urology, and Reproductive Medicine (ORDPURM) Directors and Deputy Directors.
- (28) CDER/OND/Office of Therapeutic Biologics and Biosimilars (OTBB) Director and Deputy Director.
- (29) CDER/Office of Pharmaceutical Quality (OPQ) Director and Deputy Director.
- (30) CDER/OPQ/Office of Biotechnology Products (OBP) Director and Deputy Director.
- (31) CDER/OPQ/Office of Lifecycle Drug Products (OLDP) Director and Deputy Director.

- (32) CDER/OPQ/Office of New Drug Products (ONDP) Director and Deputy Director.
- (33) CDER/OPQ/Office of Pharmaceutical Manufacturing Assessment (OPMA) Director and Deputy Director.
- (34) CDER/OPQ/Office of Policy for Pharmaceutical Quality (OPPQ) Director and Deputy Director.
- (35) CDER/OPQ/Office of Program and Regulatory Operations (OPRO) Director and Deputy Director.
- (36) CDER/OPQ/Office of Quality Surveillance (OQS) Director and Deputy Director.
- (37) CDER/OPQ/Office of Testing and Research (OTR) Director and Deputy Director.
- (38) CDER/Office of Regulatory Policy (ORP) Director and Deputy Director.
- (39) CDER/ORP/Division of Information Disclosure Policy (DIDP) Director.
- (40) CDER/Office of Surveillance and Epidemiology (OSE) Director and Deputy Director.
- (41) CDER/OSE/Office of Medication Error Prevention and Risk Management (OMEPRM) Director and Deputy Director.
- (42) CDER/OSE/Office of Pharmacovigilance and Epidemiology (OPE) Director and Deputy Director.
- (43) CDER/Office of Translational Sciences (OTS) Director and Deputy Director.
- (44) CDER/OTS/Office of Biostatistics (OB) Director and Deputy Director.
- (45) CDER/OTS/Office of Clinical Pharmacology (OCP) Director and Deputy Director.
- (46) CDER/OTS/Office of Study Integrity and Surveillance (OSIS) Director and Deputy Director.
- (47) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, Deputy Center Director for Policy, and Associate Director for International Affairs.
- (48) CDRH/Office of Policy (OP) Director and Deputy Director.
- (49) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Principal Deputy Director.
- (50) CDRH/OPEQ/Office of Health Technology I (OHT I) Director.
- (51) CDRH/OPEQ/Office of Health Technology II (OHT II) Director.
- (52) CDRH/OPEQ/Office of Health Technology III (OHT III) Director.
- (53) CDRH/OPEQ/Office of Health Technology IV (OHT IV) Director.

- (54) CDRH/OPEQ/Office of Health Technology V (OHT V) Director.
- (55) CDRH/OPEQ/Office of Health Technology VI (OHT VI) Director.
- (56) CDRH/OPEQ/Office of In Vitro Diagnostics and Radiological Health (OIR) Director.
- (57) CDRH/Office of Strategic Partnerships and Technology Innovation (OSPTI) Director and Deputy Director.
- (58) Center for Food Safety and Applied Nutrition (CFSAN) Director and Deputy Directors.
- (59) CFSAN/International Affairs Staff (IAS) Director and Deputy Director.
- (60) CFSAN/Office of Coordinated Outbreak Response and Evaluation (CORE) Director and Deputy Director.
- (61) CFSAN/Office of Compliance (OC) Director and Deputy Director.
- (62) CFSAN/Office of Regulations and Policy (ORP) Director and Deputy Director.
- (63) Center for Tobacco Products (CTP) Director and Deputy Director.
- (64) CTP/Office of the Center Director (OCD)/Stakeholder Relations Office (SRO) Director.
- (65) CTP/Office of Compliance and Enforcement (OCE) Director and Deputy Directors.
- (66) Center for Veterinary Medicine (CVM) Director and Deputy Directors.
- (67) CVM/Office of the Center Director (OCD)/International Staff (IS) Director.
- (68) CVM/Office of New Animal Drug Evaluation (ONADE) Director and Deputy Director.
- (69) CVM/Office of Surveillance and Compliance (OSC) Director and Deputy Directors.
- (70) Office of the Chief Scientist (OC) Chief Scientist.
- (71) OCS/National Center for Toxicological Research (NCTR) Director, Associate Director for Executive Programs and Services, and Associate Director for Research.
- (72) OCS/NCTR/Office of Management (OM) Associate Director for Management.
- (73) OCS/NCTR/Office of Research (OR) Associate Director for Regulatory Activities.
- (74) OCS/Office of Counterterrorism and Emerging Threats (OCET) Director.
- (75) pOffice of Food Policy and Response (OFPR) Deputy Commissioner, Associate Commissioners, Chief Medical Officer, and Intergovernmental Affairs and Partnerships Director.

- (76) Office of Policy, Legislation, and International Affairs (OPLIA) Deputy Commissioner.
- (77) OPLIA/Office of Global Policy and Strategy (OGPS) Associate Commissioner.
- (78) Office of Regulatory Affairs (ORA) Associate Commissioner for Regulatory Affairs and Deputy Associate Commissioner for Regulatory Affairs.
- (79) ORA/Office of Enforcement and Import Operations (OEIO) Director and Deputy Directors.
- (80) ORA/OEIO/Division of Import Operations Management (DIOM) Director.
- (81) ORA/Office of Human and Animal Food Operations (OHAFO) Assistant Commissioner for Human and Animal Food Operations and Senior Advisor.
- (82) ORA/OHAFO/Office of Human and Animal Food Operations – East (OHAFOE) Director and Deputy Director.
- (83) ORA/OHAFO/Office of Human and Animal Food Operations – West (OHAFOW) Director and Deputy Director.
- (84) ORA/Office of Medical Products and Tobacco Operations (OMPTO) Assistant Commissioner for Medical Products and Tobacco Operations and Deputy Director.
- (85) ORA/OMPTO/Office of Bioresearch Monitoring Operations (OBIMO) Director and Deputy Director.
- (86) ORA/OMPTO/Office of Biological Products Operations (OBPO) Director and Deputy Director.
- (87) ORA/OMPTO/Office of Medical Devices and Radiological Health Operations (OMDRHO) Director and Deputy Director.
- (88) ORA/OMPTO/Office of Pharmaceutical Quality Operations (OPQO) Director and Deputy Director.
- (89) ORA/OMPTO/OPQO/Division of Pharmaceutical Quality Programs (DPQP) Director.
- (90) ORA/OMPTO/Tobacco Operations Staff (TOS) Director.
- (91) ORA/Office of Partnerships and Operational Policy (OPOP) Assistant Commissioner for Partnerships and Operational Policy and Deputy Director.
- (92) ORA/OPOP/Office of Partnerships (OP) Director and Deputy Director.
- (93) ORA/OPOP/OP/Division of Integration (DI) Director and International and Federal Engagement Supervisor.
- (94) ORA/OPOP/Office of Strategic Planning and Operational Policy (OSPOP) Director and Deputy Director.

- (95) ORA/OPOP/OSPOP/Division of Information Disclosure Policy (DIDP) Director and Supervisory Government Information Specialists.
- (96) Office of Women's Health (OWH) Associate Commissioner for Women's Health.

B. The officials listed below are delegated the authority to disclose Level 2 nonpublic, pre-decisional guidance documents to foreign government officials under 21 CFR 20.89(d). Such officials may disclose such information directly or may authorize such disclosure and designate FDA staff to transmit such information to foreign government officials on their behalf whether for an individual disclosure, or a series of disclosures, at the discretion of the official:

- (1) OC Principal Deputy Commissioner.
- (2) CBER Director and Deputy Director.
- (3) CDER Director, Deputy Directors, and Associate Director for Strategic Initiatives.
- (4) CDER/OC Director and Deputy Directors.
- (5) CDER/OMP Director and Deputy Director.
- (6) CDER/OPQ Director and Deputy Director.
- (7) CDER/OPQ/OPPQ Director and Deputy Director.
- (8) CDER/ORP Director and Deputy Director.
- (9) CDER/OTS Director and Deputy Director.
- (10) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (11) CDRH/OP Director and Deputy Director.
- (12) CDRH/OPEQ Director and Principal Deputy Director.
- (13) CDRH/OPEQ/OHT I Director.
- (14) CDRH/OPEQ/OHT II Director.
- (15) CDRH/OPEQ/OHT III Director.
- (16) CDRH/OPEQ/OHT IV Director.
- (17) CDRH/OPEQ/OHT V Director.
- (18) CDRH/OPEQ/OHT VI Director.
- (19) CDRH/OPEQ/OIR Director.
- (20) CDRH/OSPTI Director and Deputy Director.
- (21) CFSAN Director and Deputy Directors.
- (22) CFSAN/IAS Director and Deputy Director.
- (23) CFSAN/OC Director and Deputy Director.

- (24) CFSAN/ORP Director and Deputy Director.
- (25) CTP Director and Deputy Director.
- (26) CVM Director and Deputy Directors.
- (27) OCS Chief Scientist.
- (28) OCS/NCTR Director and Deputy Director.
- (29) OFPR Deputy Commissioner and Associate Commissioners.
- (30) OPLIA Deputy Commissioner.
- (31) OPLIA/OGPS Associate Commissioner.
- (32) ORA Associate Commissioner for Regulatory Affairs.
- (33) ORA/OEIO Director and Deputy Director.
- (34) ORA/OPOP Assistant Commissioner for Partnerships and Operational Policy.
- (35) ORA/OPOP/OP Director and Deputy Director.
- (36) ORA/OPOP/OP/DI Director and International and Federal Engagement Supervisor.
- (37) ORA/OPOP/OSPOP Director and Deputy Director.
- (38) ORA/OPOP/OSPOP/DIDP Director and Supervisory Government Information Specialists.
- (39) OWH Associate Commissioner for Women's Health.

**2. Redelelegation.**

These officials may not further redelegate these authorities.

**3. Effective Date.**

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 9 June 2020.

<b>Status</b>	<b>Date Approved</b>	<b>Location of Change History</b>	<b>Contact</b>	<b>Approving Official</b>
Initial	06/09/2020	N/A	OPLIA/ OGPS	Stephen M. Hahn, M.D. Commissioner of Food and Drugs