SMG 1410.112

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Human Drugs and Animal Drugs

Requests for Records or Other Information from Establishments Engaged in Manufacturing, Preparing, Propagating, Compounding, or Processing of Drugs

Effective Date: 10 May 2021

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to requesting and confirming receipt of records or other information from establishments under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)):

(1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.

(2) CBER/Office of Compliance and Biologics Quality (OCBQ) Director and Deputy Director.

(3) CBER/OCBQ/Division of Biological Standards and Quality Control (DBSQC) Director.

(4) CBER/OCBQ/Division of Case Management (DCM) Director.

(5) CBER/OCBQ/Division of Inspections and Surveillance (DIS) Director.

(6) CBER/OCBQ/Division of Manufacturing and Product Quality (DMPQ) Director.

(7) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.

(8) CDER/Office of Compliance (OC) Director and Deputy Director.

(9) CDER/OC/Office of Compounding Quality and Compliance (OCQC) Director.

(10) CDER/OC/OCQC/Division of Compounding I (DC I) Director.

(11) CDER/OC/OCQC/Division of Compounding II (DC II) Director.

(12) CDER/OC/OCQC/Division of Compounding Policy and Outreach (DCPO) Director.

(13) CDER/OC/Office of Drug Security, Integrity, and Response (ODSIR) Director.

(14) CDER/OC/ODSIR/Division of Global Drug Distribution and Policy (DGDDP) Director.

(15) CDER/OC/ODSIR/Division of Supply Chain Integrity (DSCI) Director.

(16) CDER/OC/Office of Manufacturing Quality (OMQ) Director.

(17) CDER/OC/OMQ/Division of Drug Quality I (DDQ I) Director.

(18) CDER/OC/OMQ/Division of Drug Quality II (DDQ II) Director.

(19) CDER/OC/Office of Program and Regulatory Operations (OPRO) Director.

(20) CDER/OC/OPRO/Program and Regulatory Operations Staff I (PROS I) Director.

(21) CDER/OC/OPRO/Program and Regulatory Operations Staff II (PROS II) Director.

(22) CDER/OC/OPRO/Program and Regulatory Operations Staff III (PROS III) Director.

(23) CDER/OC/Office of Scientific Investigations (OSI) Director.

(24) CDER/OC/OSI/Division of Clinical Compliance Evaluation (DCCE) Director.

(25) CDER/OC/OSI/Division of Enforcement and Postmarket Safety (DEPS) Director.

(26) CDER/OC/Office of Unapproved Drugs and Labeling Compliance (OUDLC) Director.

(27) CDER/OC/OUDLC/Division of Labeling, Registration, and Unapproved Drugs (DLRUD) Director.

(28) CDER/OC/OUDLC/Division of Unapproved Drugs and Labeling (DUDL) Director.

(29) CDER/Office of Generic Drugs (OGD) Director and Deputy Directors.

(30) CDER/OGD/Office of Bioequivalence (OB) Director.

(31) CDER/OGD/OB/Division of Bioequivalence I (DB I) Director.

(32) CDER/OGD/OB/Division of Bioequivalence II (DB II) Director.

(33) CDER/OGD/OB/Division of Bioequivalence III (DB III) Director.

(34) CDER/OGD/OB/Division of Bioequivalence Process Management (DBPM) Director.

(35) CDER/OGD/Office of Generic Drug Policy (OGDP) Director.

(36) CDER/OGD/OGDP/Division of Legal and Regulatory Support (DLRS) Director.

(37) CDER/OGD/OGDP/Division of Orange Book Publication and Regulatory Assessment (DOBPRA) Director.

(38) CDER/OGD/OGDP/Division of Policy Development (DPD) Director.

(39) CDER/OGD/Office of Regulatory Operations (ORO) Director.

(40) CDER/OGD/ORO/Division of Filing Review (DFR) Director.

(41) CDER/OGD/ORO/Division of Labeling Review (DLR) Director.

(42) CDER/OGD/ORO/Division of Project Management (DPM) Director.

(43) CDER/OGD/Office of Research and Standards (ORS) Director.

(44) CDER/OGD/ORS/Division of Quantitative Methods and Modeling (DQMM) Director.

(45) CDER/OGD/ORS/Division of Therapeutic Performance I (DTP I) Director.

(46) CDER/OGD/ORS/Division of Therapeutic Performance II (DTP II) Director.

(47) CDER/OGD/Office of Safety and Clinical Evaluation (OSCE) Director.

(48) CDER/OGD/OSCE/Division of Clinical Review (DCR) Director.

(49) CDER/OGD/OSCE/Division of Clinical Safety and Surveillance (DCSS) Director.

(50) CDER/OGD/OSCE/Division of Pharmacology and Toxicology Review (DPTR) Director.

(51) CDER/Office of Pharmaceutical Quality (OPQ) Director and Deputy Director.

(52) CDER/OPQ/Office of Biotechnology Products (OBP) Director and Deputy Director.

(53) CDER/OPQ/OBP/Division of Biotechnology Review and Research I (DBRR I) Director.

(54) CDER/OPQ/OBP/Division of Biotechnology Review and Research II (DBRR II) Director.

(55) CDER/OPQ/OBP/Division of Biotechnology Review and Research III (DBRR III) Director.

(56) CDER/OPQ/OBP/Division of Biotechnology Review and Research IV (DBRR IV) Director.

(57) CDER/OPQ/Office of Lifecycle Drug Products (OLDP) Director and Deputy Director.

(58) CDER/OPQ/OLDP/Division of Immediate and Modified Release Products I (DIMRP I) Director.

(59) CDER/OPQ/OLDP/Division of Immediate and Modified Release Products II (DIMRP II) Director.

(60) CDER/OPQ/OLDP/Division of Immediate and Modified Release Products III (DIMRP III) Director.

(61) CDER/OPQ/OLDP/Division of Liquid-Based Products I (DLBP I) Director.

(62) CDER/OPQ/OLDP/Division of Liquid-Based Products II (DLBP II) Director.

(63) CDER/OPQ/OLDP/Division of Post-Marketing Activities I (DPMA I) Director.

(64) CDER/OPQ/OLDP/Division of Post-Marketing Activities II (DPMA II) Director.

(65) CDER/OPQ/Office of New Drug Products (ONDP) Director and Deputy Director.

(66) CDER/OPQ/ONDP/Division of Biopharmaceutics (DB) Director.

(67) CDER/OPQ/ONDP/Division of Life Cycle API (DLCAPI) Director.

(68) CDER/OPQ/ONDP/Division of New Drug API (DNDAPI) Director.

(69) CDER/OPQ/ONDP/Division of New Drug Products I (DNDP I) Director.

(70) CDER/OPQ/ONDP/Division of New Drug Products II (DNDP II) Director.

(71) CDER/OPQ/ONDP/Division of New Drug Products III (DNDP III) Director.

(72) CDER/OPQ/Office of Pharmaceutical Manufacturing Assessment (OPMA) Director and Deputy Director.

(73) CDER/OPQ/OPMA/Division of Biotechnology Manufacturing (DBM) Director.

(74) CDER/OPQ/OPMA/Division of Pharmaceutical Manufacturing I (DPM I) Director.

(75) CDER/OPQ/OPMA/Division of Pharmaceutical Manufacturing II (DPM II) Director.

(76) CDER/OPQ/OPMA/Division of Pharmaceutical Manufacturing III (DPM III) Director.

(77) CDER/OPQ/OPMA/Division of Pharmaceutical Manufacturing IV (DPM IV) Director.

(78) CDER/OPQ/OPMA/Division of Microbiology Assessment I (DMA I) Director.

(79) CDER/OPQ/OPMA/Division of Microbiology Assessment II (DMA II) Director.

(80) CDER/OPQ/Office of Policy for Pharmaceutical Quality (OPPQ) Director and Deputy Director.

(81) CDER/OPQ/OPPQ/Division of Internal Policies and Programs (DIPAP) Director.

(82) CDER/OPQ/OPPQ/Division of Regulations, Guidance, and Standards (DRGS) Director.

(83) CDER/OPQ/Office of Program and Regulatory Operations (OPRO) Director and Deputy Director.

(84) CDER/OPQ/OPRO/Division of Operational Excellence, Learning, and Professional Development (DOELPD) Director.

(85) CDER/OPQ/OPRO/Division of Regulatory and Business Process Management I (DRBPM I) Director.

(86) CDER/OPQ/OPRO/Division of Regulatory and Business Process Management II (DRBPM II) Director.

(87) CDER/OPQ/OPRO/Division of Regulatory and Business Process Management III (DRBPM III) Director.

(88) CDER/OPQ/Office of Quality Surveillance (OQS) Director, Deputy Directors, Associate Director for Regulatory Affairs, Associate Director for Science and Communications, and Senior Scientific Advisor.

(89) CDER/OPQ/OQS/Division of Quality Data Science (DQDS) Director.

(90) CDER/OPQ/OQS/Division of Quality Intelligence I (DQI I) Director.

(91) CDER/OPQ/OQS/Division of Quality Intelligence II (DQI II) Director.

(92) CDER/OPQ/Office of Testing and Research (OTR) Director and Deputy Director.

(93) CDER/OPQ/OTR/Division of Complex Drug Analysis (DCDA) Director.

(94) CDER/OPQ/OTR/Division of Pharmaceutical Analysis (DPA) Director.

(95) CDER/OPQ/OTR/Division of Product Quality Research (DPQR) Director.

(96) Center for Veterinary Medicine (CVM) Director and Deputy Directors.

(97) CVM/Office of Surveillance and Compliance (OSC) Director and Deputy Directors.

(98) CVM/OSC/Division of Compliance (DC) Director and Deputy Director.

(99) CVM/OSC/Division of Animal Feeds (DAF) Director and Deputy Director.

(100) CVM/Office of New Animal Drug Evaluation (ONADE) Director and Deputy Director.

(101) CVM/ONADE/Division of Manufacturing Technologies (DMT) Director and Deputy Director.

(102) Office of Regulatory Affairs (ORA) Associate Commissioner for Regulatory Affairs and Deputy Associate Commissioner for Regulatory Affairs.

(103) ORA/Office of Medical Products and Tobacco Operations (OMPTO) Assistant Commissioner for Medical Products and Tobacco Operations and Deputy Director.

(104) ORA/OMPTO/Office of Biological Products Operations (OBPO) Director and Deputy Director.

(105) ORA/OMPTO/OBPO/Division of Biological Products Operations I (DBPO I) Director.

(106) ORA/OMPTO/OBPO/Division of Biological Products Operations II (DBPO II) Director.

(107) ORA/OMPTO/Office of Pharmaceutical Quality Operations (OPQO) Director and Deputy Director.

(108) ORA/OMPTO/OPQO/Division of Pharmaceutical Quality Operations I (DPQO I) Director.

(109) ORA/OMPTO/OPQO/Division of Pharmaceutical Quality Operations II (DPQO II) Director.

(110) ORA/OMPTO/OPQO/Division of Pharmaceutical Quality Operations III (DPQO III) Director.

(111) ORA/OMPTO/OPQO/Division of Pharmaceutical Quality Operations IV (DPQO IV) Director.

2. Redelegation.

These officials may not redelegate these authorities.

3. Effective Date.

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 10 May 2021.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	09/08/2014	N/A	OMPT/ CDER/OM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	05/10/2021	N/A	CDER/OP	Janet Woodcock, M.D. Acting Commissioner of Food and Drugs
Change	05/27/2021	Sect. 1.A.(20) – (22)	CDER/OP	Janet Woodcock, M.D. Acting Commissioner of Food and Drugs