Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book

Speaker Biographies

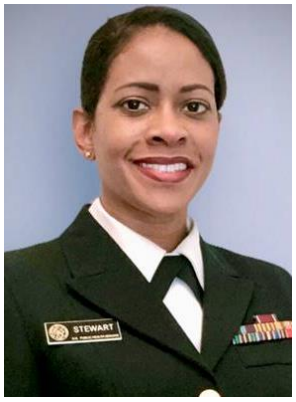
In order of appearance.

Sally Choe, PhD

Director
Office of Generics Drugs (OGD) | CDER

Sally Choe, PhD, serves as the director of the Office of Generic Drugs (OGD), where she is the principal authority on all matters related to generic drug review, and scientific advisor to the Commissioner and other agency officials. Previously, Dr. Choe served as deputy director of the Office of Study Integrity and Surveillance (OSIS) in CDER's Office of Translational Sciences (OTS). With more than 18 years of experience in global drug development, Dr. Choe is an accomplished leader in both government and the private sector. She is a recognized expert in drug review, clinical pharmacology, biopharmaceutics, and pharmacokinetics. Dr. Choe was senior director at PAREXEL International Corporation, overseeing the Asia-Pacific region and Japan offices, as well as managing the global Vice President Technical consultant group. From 2006 - 2011, Dr. Choe was leader of the metabolism and endocrinology team in FDA's Office of Clinical Pharmacology, OTS. She supervised scientists in clinical and pharmacology review and evaluation of New Drug Applications (NDAs), Biologics License Application (BLAs), and investigational new drug applications (INDs), including original submissions and amendments. Prior to FDA, she also was a clinical pharmacology manager at Pfizer Global Research and a research investigator at Bristol-Myers Squibb. Dr. Choe earned her master's and doctoral degrees in pharmaceutics from the University of Michigan and her bachelor's degree in electrical engineering from Virginia Polytechnic Institute and State University.

Kendra Stewart



CAPT, USHPS
Supervisor, Orange Book Staff
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP)
OGD | CDER

Captain Kendra Stewart is the Supervisor of the Orange Book Staff within the Office of Generic Drug Policy (OGDP) at the U.S. Food and Drug Administration (FDA). She began her career in 2001 as a pharmacist for the Veterans Affairs Hospital. In 2003, she was commissioned as a Lieutenant in the US Public Health Service and joined the FDA as an Assistant Pharmacist on the Orange Book Staff until 2008, when she joined what was then known as the Labeling Review Branch within the Office of Generic Drugs (OGD). In 2013, Captain Stewart returned to the Orange Book staff where she currently holds the position of Senior Supervisor Regulatory Affairs, Orange Book. In her work with the Orange Book she holds direct supervisory responsibility for the staff and is involved extensively with the Orange Book publication, various policy issues, public outreach and education on drug substitution. Captain Stewart graduated from Florida A&M University in 2001 with a Doctor of Pharmacy degree.

Camille Smith

DLRS | OGDP | OGD

Camille Smith works in the Office of Generic Drug Policy as an Orange Book Staff pharmacist. Camille previously worked in CDER's Office of Pharmaceutical Quality as a project manager and the Office of Compliance as a consumer safety officer. Camille received her Doctor of Pharmacy Degree from the University of Maryland, Baltimore and has also earned the Regulatory Affairs Certification, RAC (US).

Kun Shen

CDR, USPHS
DLRS | OGDP | OGD | CDER

CDR Kun Shen is a pharmacist currently serving as a policy advisor since 2015 in the Office of Generic Drug Policy under the Division of Legal and Regulatory Support. His areas of expertise are in drug shortage and Orange Book. Kun graduated with a Doctor of Pharmacy from the University of Maryland, Baltimore in 2001 and is board certified in Pharmacotherapy. Kun joined the FDA in 2008 after serving six years as a clinical research pharmacist at the National Institutes of Health. Kun served as a regulatory project manager for various offices at the FDA before joining OGDP.

Eunice Chung-Davies, PharmD

CDR, USPHS
Division of User Fee Management and Budget Formulation (DUFMBF)
Office of Management (OM) | CDER

Commander Eunice Chung-Davies received her Doctorate of Pharmacy from Rutgers University in NJ in 2006. She then completed a fellowship with the Rutgers Pharmaceutical Fellowship Program in 2008. In 2008, she first joined the FDA as a Regulatory Project Manager for the Division of Pulmonary, Allergy, and Rheumatology Products. In 2012, she joined the Office of Prescription Drug Promotion, where she served as a Regulatory Review Officer and Team Leader. In 2016, she joined the Division of User Fee Management and Budget Formulation within the Office of Management, where she is currently Team Leader of the Fees Team within the Brands Branch.

Elizabeth Friedman, J.D.

Division of Policy Development (DPD) | OGDP | OGD | CDER

Elizabeth Giaquinto Friedman is a regulatory counsel in the Office of Generic Drug Policy's Division of Policy Development. Before joining OGD in 2013, Elizabeth worked in CDER's Office of Executive Programs for five years. Elizabeth received her B.A. in International Relations from Lehigh University and holds J.D. and LL.M. degrees from Seton Hall University School of Law.

Alicia Chen

DLRS | OGDP | OGD | CDER

Alicia Chen has been with the FDA and the Office of Generic Drugs (OGD) since 2014. She initially joined OGD as a discipline project manager, and in 2016 joined the Orange Book team as a marketing protections pharmacist. Alicia has been the team lead for the Orange Book staff since 2019. She has prior experience working in the hospital and retail settings.

Janice Weiner, J.D.

Division of Regulatory Policy I (DRPI)
Office of Regulatory Policy (ORP) | CDER

Janice Weiner is a Principal Regulatory Counsel in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. Ms. Weiner works on a broad range of regulatory policy issues related to pharmaceuticals, and led the FDA working group that developed the proposed and final regulations to implement portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Ms. Weiner received an A.B. from Georgetown University, a J.D. from Harvard Law School, and an M.P.H. from Harvard School of Public Health. Prior to joining FDA in 2005, she practiced law in Washington, DC.

Mary Ann Holovac, R.Ph.

Division of Regulatory Policy (DRP)
Office of New Drug Policy (ONDP)
Office of New Drugs (OND)

Mary Ann Holovac is a retired PHS Commissioned Corps pharmacist and is currently a clinical analyst and program coordinator for FDA's 505(b)(2) program. Mary Ann worked with the Orange Book for many years before joining the Office of New Drugs 505(b)(2) group in 2013. Mary Ann designed, developed and programmed the web-interface of the first version of the searchable Orange Book database in 1997 bringing the Orange Book from a hardcopy to the on-line searchable database still in use today.

Andrew Coogan

LCDR, USPHS
DLRS | OGDP | OGD | CDER

Andrew Coogan is a Lieutenant Commander in the United States Public Health Service and a member of the Patent and Exclusivity Team (PET) in the Office of Generic Drug Policy. He joined FDA in 2014 as a Regulatory Project Manager and has been a member of the PET since 2018. Before joining FDA, he was a clinical pharmacist with Indian Health Service on the Navajo Reservation in Arizona. He received his Bachelor of Science in Pharmaceutical Science and his Doctorate of Pharmacy from the University of Pittsburgh and is a Master of Public Health Candidate at the Johns Hopkins Bloomberg School of Public Health.

Jennifer Gerton

Office of the Chief Counsel (OCC)

Ms. Gerton works in FDA's Office of the Chief Counsel, focusing on legal issues related to generic drugs, 505(b)(2) applications, and biosimilar biological products.

Truong Quach

DLRS|OGDP|OGD

Truong Quach is a pharmacist working in the Office of Generic Drugs, Division of Legal and Regulatory Support, Orange Book and has been with the FDA since 2014. Truong received his bachelor's in chemistry from the University of California, Irvine. After graduation, he attended Massachusetts College of Pharmacy in Boston where he graduated with a Pharm.D. in 2005. Prior to joining the FDA, Truong practiced pharmacy in both community and hospital settings for over 9 years where he worked as a pediatric NICU clinical pharmacist at the Walter Reed National Military Medical Center. As an Orange Book Pharmacist, he helps the Orange Book publication by identifying drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information. Truong is also responsible for reviewing approved labeling and the content of clinical data in new drug original and efficacy supplement approvals to make Hatch-Waxman exclusivity determinations. In his free time, he loves the great outdoors and travel with his family.

Nisha Shah, J.D.

Division of Regulatory Policy I (DRPIV)
Office of Regulatory Policy (ORP)

Nisha Shah is a Senior Regulatory Counsel in CDER's Office of Regulatory Policy, which she joined in 2012. She focuses on legal and regulatory issues involving 505(b)(2) applications, 5-year and 3-year exclusivities for new drug applications, antibiotic drug development, and drug labeling, among other matters. She serves on CDER's 505(b)(2) clearance committee, which reviews each original 505(b)(2) application or efficacy supplement for legal and regulatory issues before an action is taken on the application or supplement. She is also a member of CDER's Exclusivity Board, which focuses on complex 5-year and 3-year exclusivity matters. Prior to joining CDER, she was an associate attorney at two prominent FDA and health care law firms in Washington, DC.

Christopher Pruitt, J.D.

Director
DLRS | OGDP | OGD | CDER

Christopher Pruitt is the director of the Division of Legal and Regulatory Support in the Office of Generic Drug Policy. He manages an interdisciplinary team of lawyers, pharmacists, and other professionals who provide day-to-day support to the Office of Generic Drugs on legal, regulatory, and policy issues affecting the regulation of generic drugs. He works on a wide range of issues related to the Hatch-Waxman Amendments, including approval requirements for generic drugs, 180-day generic drug exclusivity, new drug exclusivities, and citizen petitions. Prior to joining OGD, Mr. Pruitt was a staff attorney in the FDA Office of Chief Counsel and practiced food and drug law as an associate at Covington & Burling LLP.

Katie Schumann

Division of Regulatory Policy (DRP)
Office of New Drug Policy (ONDP)
OND | CDER

Katie Schumann, MS, is the Deputy Director of the Division of Regulatory Policy in the Office of New Drug Policy, OND, CDER, FDA. In this role, she assists with daily management of the Division. The Division of Regulatory Policy provides regulatory policy support to OND staff and the new drug regulatory program, administers the 505(b)(2) NDA program, and serves as an OND-wide resource for the guidance development process. She previously served as the Associate Director for Regulatory Affairs in the Office of Antimicrobial Products, OND, CDER. She earned her undergraduate degree from the University of Virginia and her master's degree in Bioscience Regulatory Affairs from Johns Hopkins University.

Aaron Friedman, J.D.

Office of Orphan Products Development (OOPD)
Office of Clinical Policy and Programs (OCPP)
CDER

Aaron Friedman is a Senior Regulatory Counsel in the Office of Orphan Products Development. Aaron has worked in OOPD since 2016 on legal and policy matters related to the Orphan Drug Designation Program, the Rare Pediatric Disease Priority Review Voucher Program, and OOPD's grants programs. Much of Aaron's work has focused on orphan drug exclusivity issues, including complex exclusivity matters involved in litigation and citizen petitions. Prior to joining OOPD, Aaron worked in FDA's Office of Regulatory Affairs and the Center for Tobacco Products. Aaron received his BA from the University of Virginia, and JD from the University of Virginia School of Law.

Kristiana Brugger, J.D.

Division of Regulatory Policy IV (DRPIV) Office of Regulatory Policy (ORP) | CDER

Kristiana Brugger is a regulatory counsel in CDER's Office of Regulatory Policy, which she joined in 2011 after several years as a litigation attorney. Her areas of expertise at FDA include pediatrics law and policy (including the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act), expedited drug development programs, priority review voucher programs, and regulatory policy pertaining to guidance development, among others. She is a member of the Pediatric Review Committee, which provides review of, and recommendations regarding, pediatric development plans under PREA and written requests under BPCA; she also advise the Pediatric Exclusivity Board regarding issues pertaining to pediatric exclusivity and written request fulfillment.

Jonathan Hughes, J.D.

DPD | OGDP | OGD | CDER

Jonathan Hughes is a regulatory counsel in the Office of Generic Drug Policy, Office of Generic Drugs (OGD). Prior to joining the FDA, he was with the Department of Veterans Affairs. Jonathan earned his BA in Political Science from Davidson College and his JD from Washington & Lee University.

Mindy Ehrenfried, J.D.

DPD | OGDP | OGD | CDER

Mindy Ehrenfried is a regulatory counsel in the Office of Generic Drug Policy (OGDP), Office of Generic Drugs (OGD). Before joining OGDP's Division of Policy Development in May 2019, Ms. Ehrenfried worked as a patent litigator for over nine years, specializing in patent disputes arising under the Hatch-Waxman Amendments and the Biologics Price Competition and Innovation Act of 2009. She received her JD, MS, and BS from the University of Maryland.

James Myers, J.D.

Director
DRP | ONDP | OND | CDER

James Myers is currently the Director of the Division of Regulatory Policy, Office of New Drug Policy, Office of New Drugs, CDER. The Division of Regulatory Policy (DRP) helps oversee new drug regulatory policy within OND, including administering the 505(b)(2) NDA program and leading the development of regulatory policy within OND. James previously served as a regulatory counsel within the Office of Generic Drug Policy, where he worked on a number of legal and regulatory issues affecting the generics industry. Prior to coming to FDA in 2014, James worked in private practice at a large international law firm in Washington, D.C.

James Hanratty, J.D.

DPD | OGDP | OGD | CDER

James Hanratty is a regulatory counsel in the Office of Generic Drug Policy, Office of Generic Drugs (OGD). Before joining OGD in September 2019, Mr. Hanratty worked at FDA's Center for Tobacco Products providing legal advice on compliance and enforcement issues. He holds a JD degree from the University of Baltimore School of Law and a BA from the University of Maryland.

Timothy Kim

DLRS | OGDP | OGD | CDER

Timothy Kim, PharmD has been a member of the Orange Book since 2014, and currently serves as a reviewer for Orange Book publication content, patent submissions, and Orange Book IT projects. He has worked on the launch of the Orange Book mobile application, Orange Book website enhancements, in addition to serving as a reviewer for controlled correspondences related to RLD and RS inquiries.

Susan Levine, J.D.

Deputy Director
DPD | OGDP | OGD | CDER

Ms. Levine currently serves as the Deputy Director of the Division of Policy Development in the Office of Generic Drug Policy where she leads development and implementation of policies for the generic drug program. Prior to this role, she was a Regulatory Counsel in the Office of Generic Drug Policy's Division of Legal and Regulatory Support where she resolved application-specific regulatory issues. She began her FDA career as a Review Chemist in the Office of Generic Drugs where she reviewed abbreviated new drug applications with a variety of dosage forms including topicals, injectables, ophthalmics, otics, and immediate release tablets.

Maryll W. Toufanian, J.D.

Director
OGDP

Maryll W. Toufanian, J.D., serves as Director of FDA's Office of Generic Drug Policy. In this role, she oversees the development and implementation of regulatory policy for the generic drug program, and the agency's publication of Approved Drug Products With Therapeutic Equivalence Evaluations, or the "Orange Book." Ms. Toufanian is a recognized agency expert on matters concerning the Hatch-Waxman Amendments related to exclusivity and patents, the legislative and regulatory landscape for generic drugs, including scientific approval requirements and novel complex product considerations, and FDA's implementation of the Generic Drug User Fee Amendments program. She also is an agency lead on FDA's Drug Competition Action Plan, a key effort to increase access to medicines and lower high drug prices. Prior to joining the generic drug program, Ms. Toufanian served as Associate Chief Counsel for Drugs in FDA's Office of Chief Counsel, concentrating on generic and biosimilar product regulation and related litigation. She came to the Agency from Zuckerman Spaeder LLP, where she focused on food and drug and criminal defense matters. Ms. Toufanian began her legal career at Willkie Farr & Gallagher LLP, and clerked for the United States District Court for the District of Columbia. She earned her J.D., cum laude, from New York University School of Law, an M.A. in English Literature from the University of Texas at Austin, and her B.A. with High Distinction from the University of Michigan.