Keith Flanagan

Keith Flanagan is Director of the Office of Generic Drug Policy (OGDP) in FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. OGDP provides leadership and direction in the development of regulations, policies and procedures concerning generic drugs and advice concerning Hatch-Waxman patent and exclusivity matters, application-specific matters, and statutory and regulatory requirements related to generic drugs. He previously served as a Senior Regulatory Counsel in FDA's Office of Regulatory Affairs.

Before joining FDA, Keith served on the U.S. Senate Health Committee staff for eight years, most recently as Senior Health Counsel. He co-authored reforms of food, drug, biologic and device regulatory laws. Before serving on Congressional staff, Keith practiced corporate and intellectual property law at a large global law firm.

He earned his BA from Colgate University and his JD from the University of Southern California Law School.