

## John K. Jenkins, MD

### Principal, Drug and Biological Products

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**BACKGROUND** • 25 years at FDA, member of senior leadership in CDER for 15 years

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**SPECIALTY** • Drug and Biological Products

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**EXPERIENCE** • Oversight of drug regulation across all therapeutic areas within CDER

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Dr. John Jenkins joins Greenleaf Health as Principal, Drug and Biological Products, following a distinguished 25-year career at the Food and Drug Administration (FDA). John received numerous awards from the FDA and external groups for his work on behalf of patients and his contributions to public health.

As Director of the Office of New Drugs (OND) at FDA's Center for Drug Evaluation and Research (CDER) from 2002 to 2017, John was responsible for more than 1,000 agency employees and 19 product review divisions. During that time, he oversaw the review of thousands of new drug applications and biological licensing applications as well as the approval of more than 400 new molecular entities. John was a critical figure in the development and implementation of programs under the Prescription Drug User Fee Act and implementation of the statutes and regulations that guide innovative drug development and regulation. John also played a leading role in implementing the biosimilar biologics program in CDER under the Biologics Price Competition and Innovation Act and the Biosimilars User Fee Act, including approval of four biosimilar applications.

John began his FDA career in 1992, where he was a medical officer in the Division of Oncology and Pulmonary Drug Products. He subsequently served as Pulmonary Medical Group Leader and Acting Division Director before being appointed as Director of the Division of Pulmonary Drug Products in 1995. He became the Director of the Office of Drug Evaluation II in 1999 and remained in that position until he was appointed Director of OND in 2002.

John received his undergraduate degree in biology from East Tennessee State University in 1979 and his medical degree from the University of Tennessee at Memphis in 1983. He completed his postgraduate medical training in internal medicine, pulmonary disease, and critical care medicine at Virginia Commonwealth University/Medical College of Virginia (MCV) from 1983 until 1988. John is Board Certified in internal medicine and pulmonary diseases by the American Board of Internal Medicine. Following completion of his medical training, John joined the faculty of MCV as an Assistant Professor of Pulmonary and Critical Care Medicine and as a Staff Physician at the Hunter Holmes McGuire VA Medical Center in Richmond, Virginia.