CDER Staff:

I am delighted to inform you that, effective today, Kathleen (“Cook”) Uhl, M.D., will serve as acting director of the Office of Generic Drugs (OGD) while we initiate a nationwide search for a permanent director. Dr. Uhl most recently served as the senior advisor to the director for OGD.

Dr. Uhl brings a wealth of regulatory and medical policy, scientific, and management experience to the position. In her fifteen years with FDA, Dr. Uhl has become widely-regarded both inside and outside of the Agency as a compassionate, committed, and dedicated leader. Because of her strong management skills and extensive expertise in clinical pharmacology, I am confident in her abilities to lead OGD during a time of transition as we work to evolve quality throughout the Center and implement the Generic Drug User Fee Amendments of 2012.

Dr. Uhl began her FDA career in 1998 as a medical officer in what is now CDER’s Office of Clinical Pharmacology. She has served in numerous positions at FDA, including five years as the assistant commissioner for Women’s Health and as director of FDA’s Office of Women’s Health (OWH). Among her many accomplishments, she is credited with forging new relationships with other federal agencies and the scientific community by establishing a cross-Agency Women’s Health Advisory Council to more effectively identify, communicate, and act on key women’s health issues in the Agency -- and to more closely align OWH’s scientific program with Agency scientific initiatives.

Dr. Uhl returned to CDER in 2010 to serve as deputy director, Office of Medical Policy (OMP) -- a position she held until January of this year. She provided exemplary leadership to OMP during a time of extraordinary change and growth as OMP underwent a major organizational change by becoming a “Super office” -- an office that houses subordinate offices within its organizational structure. Dr. Uhl played a critical role in facilitating OMP’s significant growth in personnel and expanded scope of operations. Further, she was instrumental in FDA’s negotiations with industry for the authorization of the new Biosimilar User Fee Act of 2012 (BsUFA), which was enacted on July 9, 2012, as part of the Food and Drug Administration Safety and Innovation Act. Additionally, Dr. Uhl has extensive knowledge of current quality and risk management processes, as well as standards relevant to FDA’s laws and regulations.

Dr. Uhl received her medical degree from the Medical College of Pennsylvania and completed residency training in family medicine with subsequent fellowship training in medical research and clinical pharmacology. She has held a variety of leadership positions with the American Society of Clinical Pharmacology and Therapeutics (ASCPT), to include serving on their board of directors and as an associate editor for their journal. Further, in 2008 she received ASCPT’s distinguished service award for her outstanding efforts in advancing clinical pharmacology and therapeutics.

Before joining the Agency, she was a clinical investigator and clinician at Walter Reed Institute of Research and Walter Reed Army Medical Center. She retains faculty appointments as associate professor in family medicine and internal medicine at the Uniformed Services University and is a retired officer of the United States Public Health Service Commissioned Corps.

Please join me in welcoming Dr. Uhl to this position. We are fortunate to have someone with her expertise, experience, and abilities leading OGD at this critical juncture.

Janet Woodcock