



NAME: Mary Ross Southworth, Pharm.D.

JOB TITLE: Deputy Director for Safety,
Office of New Drugs, Division of
Cardiovascular and Renal Products,
Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration
(FDA)

EDUCATION/DEGREES/CERTIFICATES/INSTITUTIONS:

Dr. Mary Ross Southworth received a Bachelor of Pharmacy Degree from Virginia Commonwealth University/Medical College of Virginia in 1994. She went on to obtain a Doctor of Pharmacy Degree in 1996 from the University of Toledo. After obtaining her Doctor of Pharmacy Degree, Dr. Southworth completed a Specialty Residency in Cardiology at the University of Illinois in 1997.

CURRENT JOB DESCRIPTION:

Dr. Southworth is the Deputy Director for Safety in the Division of Cardiovascular and Renal Products at the Food and Drug Administration (FDA) in Silver Spring, Maryland. As the Deputy Director of Safety, her responsibilities include managing postmarketing safety issues related to cardiovascular and renal drug and biologic products. These safety issues often require application of complex scientific expertise, integrated evaluation throughout FDA, and coordination with other Agencies because of their impact on public health. As the Deputy Director of Safety, Dr. Southworth provides scientific expertise; she also coordinates and oversees the Division's development, tracking, and follow up on all postmarketing safety issues including postmarketing studies, clinical trials, Risk Mitigation and Evaluation Strategies (REMS), safety labeling changes, and other safety communications and activities. When managing these safety issues, Dr. Southworth's goal is to ensure that each issue is handled in a way that promotes safety without reducing the benefits of the drug or biologic product.

QUALIFYING SKILLS FOR CURRENT POSITION:

Dr. Southworth joined the FDA in 2004 as a Pharmacist/Safety Evaluator in the Office of Surveillance and Epidemiology, Division of Adverse Events Analysis I. As a Safety Evaluator, Dr. Southworth reviewed cardiovascular and renal postmarketing safety issues. In addition, Dr. Southworth completed a fellowship in Leadership Development through the Council for Excellence in Government.

Prior to joining FDA, Dr. Southworth was a Clinical Assistant Professor of Pharmacy Practice and Clinical Assistant Professor of Medicine at the University of Illinois at Chicago. She has conducted extensive research and authored numerous publications in

the area of cardiology. In addition, she maintains an appointment as an Adjunct Clinical Assistant Professor of Pharmacy Practice at the University of Illinois at Chicago and is a peer reviewer for *Pharmacotherapy* and *The American Journal of Cardiology*.

MOST REWARDING PROFESSIONAL EXPERIENCE:

Dr. Southworth has had many rewarding professional experiences in her previous clinical practice and in her current position. She especially enjoys being involved in the FDA's universal approach to patient safety and having an impact on the public health of many Americans.

OTHER PROFESSIONAL INTERESTS:

Dr. Southworth enjoys learning more about and developing data sources and methods to investigate postmarketing safety issues.

by LCDR Richardae T. Araojo