



Janet Woodcock, MD

Director of the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

Janet Woodcock is the director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). The center makes sure that safe and effective drugs are available to improve the health of people in the United States.

Dr. Woodcock and her center:

- evaluate prescription and over the counter drugs before they can be sold and oversee their testing in clinical trials
- provide health care professionals and patients the information they need to use medicines wisely
- ensure that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks
- take action against unapproved, contaminated, or fraudulent drugs that are marketed illegally

"New drugs—and new uses for older drugs—save lives, reduce suffering, and improve the quality of life for millions of Americans," says Dr. Woodcock. "I am continually challenged to make sure that FDA's regulatory process remains the world's gold standard for drug approval and safety."

Dr. Woodcock has led many of FDA's drug initiatives. She introduced the concept of risk management in 2000 as a new approach to drug safety. Since 2002, she has led the "Pharmaceutical Quality for the 21st Century Initiative," FDA's highly successful effort to modernize drug manufacturing and its regulation. In 2004, she introduced FDA's "Critical Path" Initiative, which is designed to move medical discoveries from the laboratory to consumers more efficiently.

Most recently, Dr. Woodcock launched the "Safety First" and "Safe Use" initiatives designed to improve drug safety management within and outside FDA, respectively.

Dr. Woodcock previously served as FDA's deputy commissioner and chief medical officer. She also led CDER as director from 1994–2005. Prior to joining CDER, Dr. Woodcock oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis in her position as director of

the Office of Therapeutics Research and Review in FDA's Center for Biologics Evaluation and Research (CBER).

Dr. Woodcock received her medical degree from Northwestern University Medical School, and her undergraduate degree from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco. She joined FDA in 1986.