



Barbara Buch, M.D.

Associate Director for Medicine, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration

Dr. Buch joined CBER in December 2010 as the Associate Director for Medicine in the immediate office of the Center Director. Dr. Buch is a fellowship-trained Orthopaedic surgeon who came to FDA in 2001 on a sabbatical from private practice as a clinical consultant for the Orthopaedic Devices Branch in the Office of Device Evaluation in the Center for Devices and Radiologic Health. After graduating from the University of Delaware with a Bachelor of Science, she completed her training at the University of Maryland Medical School followed by residency training in General and Orthopaedic Surgery at the Union Memorial Hospital in collaboration with Johns Hopkins University and Maryland Institute for Emergency Medical Services Systems (Shock Trauma) in Baltimore, MD. Following residency, Dr. Buch completed a Foot and Ankle fellowship in Brisbane, Australia and subsequently received her MBA certificate at the Johns Hopkins School of Professional studies in the Business of Medicine. Her clinical interests include women's health and osteoporosis, foot and ankle Orthopaedic medicine and Pediatric Musculoskeletal Disease and Orthopaedics as well as advancements in the treatment of arthritic degenerative conditions.

Her diverse experience at FDA includes clinical review activities in both a biologics/drug review branch at CDER/ Office of New Drug Evaluation in the Division of Therapeutic Biologic Internal Medicine Products and in the Center for Devices and Radiologic Health (CDRH) in the Orthopaedics Devices Branch, management activities in the Office of Device Evaluation (ODE) as the Office Clinical Deputy Director and Deputy Division Director in ODE/Division of Surgical Orthopaedic and Restorative Devices, in the Commissioner's Office in the Office of Policy and Planning (OPPL) as a medical advisor to the Associate Commissioner, and as a medical officer in the Commissioners Office of Special Health Issues (OSHI). In addition to clinical review activities, Dr. Buch has been involved in policy development related to the implementation of the pediatric and clinical trials sections of FDAAA, FDASIA, and 21st Century Cures legislation, assuring scientific conduct of clinical trials and patient protection measures; staff professional development and training, and outreach to external stakeholders and the public. More recently, she chaired the FDASIA 907 Steering committee and leads the CBER Drug Development Tools initiative.