The Office of Pharmaceutical Science (OPS) is proud to announce the selection of Gregory P. Geba, M.D., M.P.H., as Director of the Office of Generic Drugs (OGD) effective July 15, 2012.

Dr. Geba has served in senior-level clinical/managerial positions in the pharmaceutical industry for the past 15 years. He most recently served as Deputy Chief Medical Officer for Sanofi US, where he provided medical and scientific leadership and managerial direction to a staff of approximately 500 multidisciplinary scientific and regulatory professionals engaged in drug development activities across all therapeutic areas, as well as to the company's field medical group.

He has contributed to the registration of more than 20 currently marketed drugs or devices across multiple therapeutic areas. In so doing, he successfully employed his working knowledge and demonstrated practical application of drug manufacturing processes, current quality and risk management processes, and standards relevant to FDA's laws and regulations. He brings extensive clinical research experience, including leading or serving as the key point in filing new drug applications, biologic license applications, and promotional studies comparing efficacy and effectiveness of novel biopharmaceuticals versus standard of care (including regimens containing branded or generic drugs), and has provided or supervised key safety updates and presentations to FDA Advisory Committees. Dr. Geba's experience also includes leading medical affairs activities while serving in a variety of senior-level positions. His scope of responsibility in those activities included contribution to the design of experimental protocols and assessment of data from pre-clinical, animal, and first-in-human studies; design, implementation, analysis, and interpretation of phase 2a proof-of-concept and 2b dose ranging studies; and production of important comparative effectiveness and safety data when assessing benefit-risk relationships during phase 3, phase 3b, and phase 4 studies.

Dr. Geba received his medical degree from the University of Navarre and his M.P.H. from the Johns Hopkins Bloomberg School of Public Health. He joins OGD at an opportune time to lead our expanding generic program into a reorganization of both structure and process to improve coordination, communication, and efficiency, as well as enhance the Office's ability to ensure that all generic drugs—which make up nearly 80 percent of prescriptions filled in the United States—are safe, effective, of high quality, and interchangeable with the brand name drug product/reference listed drug.

Please join me in welcoming Dr. Geba to this important position. We welcome the wealth of knowledge and experience that he will bring to the organization.