CDER Staff:

I want to inform you about some important proposed organizational changes for CDER. I am having a series of meetings with staff in the Office of Generic Drugs, the Office of Pharmaceutical Science, and the Office of Compliance to discuss these proposed changes in more detail.

With the historic passage of the Generic Drug User Fee Amendments of 2012 (GDUFA) and a heightened public focus on generic drugs, I am proposing to elevate the Office of Generic Drugs (OGD) to a "super Office" — an office that houses subordinate offices within its organizational structure. As a super Office, OGD would report directly to me, as do other super Offices such as the Office of New Drugs and the Office of Surveillance and Epidemiology, and a number of other CDER offices.

Generic drugs, which now make up nearly 80 percent of prescriptions filled in the United States, have come to represent affordable access to treatment for many patients. Under the proposed restructuring, OGD Director Greg Geba, M.D., would continue to lead the expanding generic program with the goal of enhancing our ability to give consumers timely access to high-quality, safe, and effective generic drugs. Effective immediately, Dr. Geba will be detailed to me in the Office of the Center Director. Mary Beth Clarke, acting director of the Office of Executive Programs, will continue to be the CDER lead on GDUFA implementation, working closely with OGD and other CDER components to implement this important program.

Also, I will be proposing other structural changes to sharpen our focus and bolster our resources around pharmaceutical quality. Quality is the underpinning of everything we do, and it is imperative that we have a drug quality program as robust as those programs we presently have for drug efficacy and drug safety.

Further, we must be strategic and have systems in place to identify and respond to quality issues before they become problems. This is especially critical due to the global nature of drug manufacturing and the sourcing of raw materials outside of the United States.

Toward these goals and underscoring our commitment to drug quality, we will be exploring the creation of a new Office of Pharmaceutical Quality (OPQ), which would be charged with overseeing quality throughout the life cycle of a drug. OPQ could take on some of the functions currently within the Office of Pharmaceutical Science (OPS), as well as other quality-related functions.
I will also propose realigning some functions from the Office of Manufacturing and Product Quality (OMPQ) in the Office of Compliance into the new OPQ. Other OMPQ functions related to enforcement and compliance would continue to reside in the Office of Compliance.
All of these changes would be part of our ongoing efforts to ensure that CDER's organizational structure supports our mission to ensure safe, effective, and high-quality drugs for the public. As a regulatory agency, we want the public to be confident that we are successfully dealing with the global economy that is constantly adding more players, more technologies, and more complexity. I believe these organizational changes would give us the foundation we need to meet these new and ever-changing challenges.

Janet Woodcock