CDER Staff:

In September 2012, with the historic passage of the Generic Drug User Fee Amendments of 2012 (GDUFA) and a heightened public focus on generic drugs, I announced plans to elevate the Office of Generic Drugs (OGD) to a “super office” – an office that houses subordinate offices within its organizational structure and which reports directly to me. This reorganization will strengthen OGD’s operations and allow the office to meet the evolving needs of generic drug review.

Today, I am excited to inform you that the OGD reorganization has been approved. Acting OGD Director Kathleen “Cook” Uhl, M.D. will continue in this role, leading our generic drug program, executing on our GDUFA performance obligations and enhancing our ability to ensure timely access to high-quality, safe, and effective generic drugs.

Generic drugs make up 84 percent of prescriptions filled in the United States and represent affordable access to treatment for many patients and consumers. These individuals depend on FDA to ensure that generic drugs perform clinically in the same way as their brand name counterpart drugs. Transforming OGD into a super office is a critical and necessary step in recognizing the importance of generic drugs to public health and our national economy. As a super office, OGD will coordinate and manage the abbreviated new drug application (ANDA) review process, provide safety, surveillance, clinical, and bioequivalence reviews for generic products, as well as contain new offices to develop policy and regulatory science for generic drugs. It will also integrate all Risk Evaluation and Mitigation Strategy (REMS) and safety labeling issues with other CDER offices.

Under GDUFA, FDA made a commitment to achieve certain performance goals. I am pleased to announce that we met or exceeded all of our Year One GDUFA goals. For example, the user fee collection system is in full operation, first-year user fees have been collected, and we exceeded our first-year hiring goals.

Next Steps

An OGD Transition Team is implementing the new office and reporting structure. OGD will have a centralized administrative support function and centralized project management for both review and policy work. OGD will have its own governance structure which means it will set its own policy and strategic agenda, ratify its own budget, resolve any disputes, and perform as an executive team. The approved structure consists of the following:

- Office of Research and Standards (includes the Division of Therapeutic Performance and the Division of Quantitative Methods and Modeling)
- Office of Bioequivalence (includes three divisions of bioequivalence and a Division of Clinical Review, which includes the OGD Safety and Surveillance Team)
- Office of Generic Drug Policy (includes the Division of Legal and Regulatory Support and the Division of Policy Development)
- Office of Regulatory Operations (includes a Division of Project Management, a Division of Labeling Review, a Division of Filing Review, and a Division of Quality Management Systems)

The Transition Leads for the above offices are Robert Lionberger, Ph.D., John Peters, M.D., Keith Flanagan, J.D., and Jason Woo, M.D., respectively. The Transition Team also includes Cook, Kristin Hornberger (acting senior management officer) and Mary Dempsey (associate director for regulatory affairs).

To keep OGD staff involved in the reorganization and informed of the implementation plans, the OGD Transition Team will hold several upcoming “lunch and learn” information sessions. These sessions will offer an opportunity to discuss the office’s future structure and its related functions with OGD staff.

As a part of the Office of Pharmaceutical Quality (OPQ) proposal, OPQ is proposed to house the product quality-related groups, including CMC and Microbiology review functions, which had previously been in OGD to ensure efficiency and consistency of standards and actions across the Center and drug product lifecycle. As OGD is now a super office, approximately 200 CMC and Microbiology reviewers in OGD will remain in the Office of Pharmaceutical Science, and then move into the new OPQ when it is established. The impact of these proposed OPQ changes will be reviewed in advance and negotiated, as applicable, with the National Treasury Employees Union (NTEU) in accordance with the FDA NTEU Collective Bargaining Agreement.

The OGD reorganization is a part of our ongoing efforts to ensure that the generic drug industry is held to standards of high quality – and our ongoing efforts to expedite the availability of safe, effective, and high quality generic drugs to patients. It also underscores our commitment to maintaining the public’s confidence in an Agency that continues to meet the ever-changing needs of the American public health.

I want to thank Cook, the OGD Transition Team, and all those individuals who have worked so hard and so diligently to make this reorganization a reality. Congratulations on achieving this important milestone.

Janet Woodcock