

CDER Staff:

As we approach the one-year anniversary of the Generic Drug User Fee Amendments of 2012 (GDUFA), I would like to recognize the important accomplishments of those who have worked to launch this program. This has been a cross-cutting Center and Agency-wide effort led by Mary Beth Clarke, and involving staff and managers from the Office of Regulatory Affairs (ORA) and most of CDER's offices. During this first year, the program has met all statutory requirements and has:

- Collected more than \$255 million in first-year user fees -- 84 percent of the FY 2013 \$299 million goal
- Hired (or have pending start dates for) 165 GDUFA new CDER hires
- Facilitated industry self-identification efforts making accurate fee calculation possible and improving the quality of generic industry supply chain information
- Made significant strides in reducing the backlog of pre-GDUFA applications and adjusting internal processes to enhance review efficiencies

After this successful launch, the program is now poised to transition to a new project and governance structure similar to the Prescription Drug User Fee Act (PDUFA). A GDUFA Steering Committee, chaired by Theresa Mullin, and comprised of CDER super office directors, a senior representative from ORA and from the Office of Commissioner's Office of Operations, will lead this next phase. The focus will now shift to implementation of review program enhancements, transforming the generic drug review process to meet the new GDUFA performance commitments.

Please join me in thanking those who worked to launch GDUFA. I appreciate your support of the GDUFA Steering Committee as we continue to successfully implement this new program and fulfill the program's goal to speed access to safe and effective generic drugs.

Janet Woodcock