

CDER Staff:

I would like to thank everyone who has contributed to the Generic Drug User Fee Amendments of 2012 (GDUFA) project thus far. Special thanks go to FDA's GDUFA Human Capital Team (HCT), which consists of people in CDER, the Office of the Commissioner, and the Office of Regulatory Affairs. Over the last 12 months, the HCT has been tasked with the hiring and training of 231 employees.

I am pleased to announce that as of August 11, the HCT has exceeded its fiscal year (FY) 2013 hiring goal for a total of 234 new employees hired.

Countless hours were spent planning, analyzing data, making decisions, and communicating among offices in order to successfully meet this goal. While the HCT serves as the managing body for the hiring and training initiative, the efforts of numerous employees from each office within CDER contributed to this achievement.

The target of 231 hires is an Agency-wide Congressional mandate, based on the agreed number of total hires for the entire GDUFA hiring initiative, lasting until September 2015. The overall goal is 921 hires, divided over three years with a 25–50–25 percent split for years one, two, and three, respectively.

I am extremely happy with this accomplishment. As hiring continues through the end of this fiscal year, planning has already begun for next fiscal year. Each additional hire positions the Agency to more efficiently progress to the next goal of 461 hires during FY 2014.

Please join me in congratulating the HCT and those employees who have contributed to this tremendous and successful effort! I am truly grateful to everyone involved.

Janet Woodcock