From: Uhl, Kathleen (CDER)
Sent: Thursday, December 11, 2014 12:00 PM
To: CDER-OGDALL; CDER-OPS-ALL; JW Direct Reports & Deputies
Subject: OGD Office of Operations (ORO) Personnel changes

Dear Colleagues,

To prepare for Year 3 of GDUFA and our first goal dates, we made many big changes fast. We moved to White Oak, reorganized and became the Office of Generics (OGD) Super Office, built new program and staffing infrastructure, flipped the switch on a new IT platform, and contributed substantially to the creation of a new Office of Pharmaceutical Quality (OPQ). Our deep, foundational restructuring will pay off dramatically. I am very proud of everyone's grit, patience, and forbearance during this transition time.

For all incoming Year 3 submissions, we are using our new IT platform to conduct reviews, manage workload, track submissions, take regulatory action, and so on. We obviously still need to hit our GDUFA goal dates, and keep our eye on the ball, and acknowledge that our new systems do work. This is a significant accomplishment.

Although much has been done to meet our GDUFA commitment related to the "Backlog" (i.e., ANDAs, ANDA amendments and ANDA supplements pending as of October 1, 2012), we still need to improve our productivity, and "move the freight" on the larger bucket of *all pre-Year 3 submissions*. This will be a major undertaking. Integrating our pre-Year 3 workload into the new IT Platform and new review processes is a large, diverse and complex task. But these submissions are important to consumers, payers and industry alike, as mentioned by the FDA Commissioner, Dr. Hamburg, at the OGD All Hands earlier today.

In GDUFA, we committed to take action on 90% of "Backlog" submissions before October 2017. I aspire to exceed our GDUFA commitments, and get to steady state on *all our pre-Year 3 workload* before October 2017. To get to a steady state, we will focus on approvals not actions, and make other business process improvements, to improve our productivity and communications with respect to the pre-Year 3 workload. Additional details will be forthcoming over the next few weeks.

To lead these improvements, I've asked Ted Sherwood to serve as Acting Director of OGD's Office of Regulatory Operations (ORO), effective Monday, December 15. Ted has a long history with CDER, starting in OGD, and he has been an integral and influential leader in OPS/OPQ over the years. His operational acumen, even temperament, and leadership were critical to OPS/OPQ's ability to attack and essentially eliminate their formerly huge pending Prior Approval Supplement (PAS) and Changes Being Effective (CBE) backlogs. He is well known for business process improvement and process integration to expand review capacity and increase productivity. His detail to OGD will leave a big gap in OPQ. Despite that, the detail is highly endorsed by Dr. Woodcock and Dr. Yu, as well as other senior Center and OGD leaders, because getting a grip on the pre-Year 3 workload is a high priority for CDER as a whole. Please welcome Ted, and assist him as he takes the helm in this critically important role.

I would be remiss if I did not recognize and salute the massive accomplishments to date of our other ORO leadership. Carol Holquist, Denise McKan, and Aaron Sigler have done an amazing job under challenging circumstances for the past several weeks and months. I applaud their tenacity, strength and hard work. They are building a world class project management team, and will continue in their current roles working with all disciplines across CDER and FDA involved in generic drug review activities to align on and assign target action dates (TADs) to all pre-year 3 ANDAs. Johnny Young and "Kojo" Awuah are aggressively tackling the filing backlog. Koung Lee and Ruby Wu are addressing the huge labeling workload and kicking out the enormous labeling supplement backlog. Randi Charbonnet and Steve Mazella are assisting the office with identification and documentation of all our processes and necessary OGD training, among other aspects of implementing a quality review system. My sincerest thanks to them for their leadership during this particularly challenging time.

Given the urgent need to prepare for GDUFA Year 3, Jason Woo essentially "took one for the team". He has been serving not only as OGD Operations Transition Lead, but also as OGD ORO's Acting Director. I want to express my gratitude for his service in these challenging positions. Actions speak louder than words, and his unselfishness in taking on tough assignments speaks for itself. Effective immediately, Dr. Woo will be leveraging his clinical, regulatory, and compliance expertise for the office and will move to the OGD Immediate Office (IO) as a Senior Medical Officer. In this role, he will interface with the Office of New Drugs (OND) and other CDER offices concerning drug product lifecycle management. In particular, he will drive forward many lingering issues that have stalled regulatory action on a number of ANDAs. This is a high priority for OGD and for the Center as we further develop a product lifecycle model for drug regulation.

In addition, the Controlled Correspondence personnel and function, currently located in the Communications Staff in the OGD IO, will move and become part of the Office of Regulatory Operations IO. The original placement of "Controls" with the Communications Staff in the IO was based largely on legacy functions of the OGD IO as well as the types of communications from industry frequently encountered by the OGD IO. Implementation of GDUFA, especially the Year 3 cohort with GDUFA goal dates, includes goal dates for Controlled Correspondence from industry. This goal date related work with Controlled Correspondence aligns more strategically with the ANDA submission tracking and monitoring function of ORO than with the Communications Staff. Subsequently, moving the "Controls" functionality to ORO will facilitate coordination of all of OGD and CDER GDUFA commitment goal date activities and responsibilities. I thank the "Controls" personnel, in particular Saundra Middleton and Marissa McNall, for their excellent work in managing the Controlled Correspondence function to date and their flexibility and understanding in adapting to this additional organizational change.

And last but by no means least, let me acknowledge with regret the upcoming retirement at the end of December of Bob West. Bob's contributions to the generic drug program are unmatched. His steadiness and judgment have guided me and many others in OGD. He has been a mentor to generations of OGD'ers, a true champion of the public health, and a class act. Thank you, Bob, for your 33 years of service to FDA and 24 years dedicated to generic drugs and OGD.

Sincerely,
Cook

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