From: A Message from the Commissioner

To: EDA-Wide

Subject: FDA/Office of the Commissioner Reorganization Implementation

Date: Thursday, March 21, 2019 11:50:06 AM





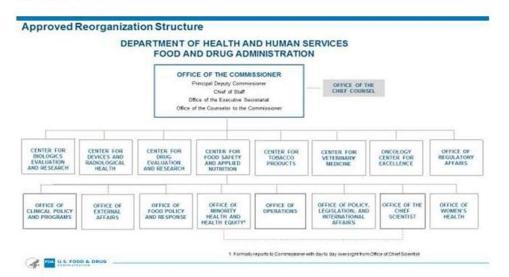
Dear Colleagues

This past summer, I wrote to you about a proposed reorganization plan for the Office of Commissioner. This plan was put forth to modernize our structure and advance our mission to protect and promote the public health as well as to ensure maximum efficiency in how we use our resources to oversee our diverse portfolio of products.

After many discussions with colleagues within the OC, the Centers, and ORA; we included several guiding principles that informed that proposal. First, we agreed that for OC to be effective, our primary role must be to advance the work of the Centers and ORA. Second, a primary focus for OC should be managing the external environment and ensuring that the FDA's public health mission is effectively executed and communicated. Further, we agreed that OC should be as efficient as possible; with very clearly defined roles and responsibilities, and minimal operational redundancy. The resulting proposed plan was shared widely within FDA. It benefited from feedback from many people.

After much coordination with leadership from across the Agency and working through the required congressional notification process, it's my pleasure to share with you that effective March 31, 2019, operational implementation of the reorganization will begin in the Office of the Commissioner.

This reorganization realigns several entities across the Agency to promote strategic priorities including changes to the Office of Policy, Planning and Legislative Affairs and the Office of External Affairs. The plan elevates the role of the Centers in support of FDA's science-driven culture, consolidates work in the Office of Operations to more effectively support the Agency's mission and strengthens our staffing and recruiting functions to hire and retain top talent and invest in our talented workforce.



Functions and responsibilities within the three directorate offices (OMPT, OFVM and OGROP) will be realigned to new offices within the Office of the Commissioner, and other areas across FDA where they can be most effective. This approach will establish a direct line between the Office of the Commissioner, Center Directors and Office leadership. This new

structure will further cement a culture of strong communications between the Office of the Commissioner, the Centers and ORA, and will support our ability to efficiently advance FDA priorities and support alignment with the Agency's overall goals.

Included in the overall reorganization proposal were also several key Centers changes. These will also be similarly implemented along with the OC reorganization. Each Center will communicate details and timing within their organizations separately, however some of the key aspects are:

- The Center for Devices and Radiological Health's reorganization establishing the Office of Product Evaluation and Quality and making changes to some existing offices.
- The Center for Drug Evaluation and Research's reorganization establishing the Office of Therapeutic Biologics and Biosimilars and making changes to some existing offices.
- The Center for Food Safety and Applied Nutrition's reorganization of the Offices of Cosmetics and Colors, and Food Additive Safety.
- The Center for Tobacco Products' reorganization of the Office of Health Communication and Education.
- · The Center for Veterinary Medicine's reorganization of the Office of New Animal Drug Evaluation.

You will also receive a message later today from Jim Sigg, FDA's Chief Operating Officer, providing more detail on the phases of the operational implementation that will impact FDA employees across the Agency, including information on updating all employee administrative codes, keying reorganization related human resource actions, updating budget information for all Centers and Offices, as well as reorganization related space planning efforts and office moves. Staff within the Office of Commissioner will be working with Centers to coordinate related activities that will impact all FDA employees.

Implementation will be rolled out in phases across the Agency and within the Centers and Offices at a thoughtful, manageable, and realistic pace so as not to interfere with day-to-day operations.

This is a very special institution. The work we engage in on behalf of the American public binds us in common purpose. We've worked many months on this proposed reorganization, and it reflects our commitment to make sure that our organizational structure is modern and efficient and reflects our efforts to best support our critical public health mission. I firmly believe the final implementation of this new structure will put the FDA on a path to advance the innovation we're seeing in medical products and food science, and the challenges we face guaranteeing our critical consumer protection mission.

Sincerely,

Dr. Scott Gottlieb

Commissioner of Food and Drugs

