From: CDER Center Director
Subject: CDER Organizational Changes Announced in 2018 Now Approved

CDER Staff:

The agency reorganization proposed in July 2018 has been approved. The reorganization aims to transform and strengthen the way FDA fulfills its public health and regulatory role. These organizational changes will take effect on March 31, 2019.

As I stated in my previous note to staff, the agency reorganization includes changes within CDER that will affect four offices: Office of New Drugs, Office of Compliance, Office of Executive Programs, and Office of Communications. The changes will give us a stronger organizational framework, which will enable us to respond to new priorities more efficiently.

I'd like to take a moment to highlight the approved changes:

Office of New Drugs (OND)

OND/Office of Therapeutic Biologics and Biosimilars

The reorganization establishes a new Office of Therapeutic Biologics and Biosimilars (OTBB) within OND. OTBB will house a Policy Staff and Scientific Review Staff and realign staff from the OND Immediate Office to OTBB.

The increasing complexities and visibility of this program require a dedicated office to efficiently and effectively achieve cross-organizational coordination and collaboration – and advance policy development for these products.

CDER is responsible for the review and continuing oversight of an increasing number of biologic marketing applications. The Biologics Price Competition and Innovation Act of 2009 was established to provide more treatment options, increase access to lifesaving medications, and potentially reduce health care costs through increased competition. It is vital that we have a framework in place to manage and sustain review coordination and policy development related to these products.

These structural changes within OND are not part of the separate effort related to the New Drugs Regulatory Program Modernization. I'll continue to share updates about the modernization as they become available.

OND/Office of Hematology and Oncology Products

The agency reorganization includes a new component – approved changes affecting OND's Office of Hematology and Oncology Products (OHOP).

As part of the reorganization, OHOP will establish a third oncology division, a second hematology division, a division of regulatory affairs, and centralized safety reporting and labeling teams.

Title III of the Cures Act, enacted into law in 2016, includes authorities the agency can use to help advance medical product development and review and create greater efficiencies and predictability. OHOP participates in numerous agency initiatives in support of the Cures Act.

With this restructure, OHOP can further its work to carry out these initiatives. OHOP, working in partnership with the agency's Oncology Center of Excellence, can apply a more unified policy approach and clinical review for all drugs, biologics, and devices used in medical oncology. This will allow us to strengthen our joint effort with industry and our stakeholders in the fight against cancer.

Office of Compliance (OC)

The Office of Compliance's organizational changes affect the Office of Unapproved Drugs and Labeling Compliance, the Office of Manufacturing Quality, and the Office of Drug Security, Integrity, and Response.

These changes will create a more robust structure that will advance its compounding program and improve our ability to shield patients from poor quality, unsafe, and ineffective drugs through compliance and enforcement actions. More specifically, the new structure will help us better address programmatic needs through our compliance strategies and programs, and through our compounding policies and operations. These improvements will allow us to further safeguard patients by ensuring industry's compliance with the new drug and misbranding requirements.

Office of Executive Programs (OEP)

The changes in the Office of Executive Programs will establish four staff groups within the Immediate Office focusing on special projects, executive secretariat matters, legislative activities, and program management and analysis – absorbing the functions of the former Division of Executive Operations. The restructuring also establishes two branches within the Division of Advisory Committee and Consultant Management to manage and oversee advisory committee and conflict of interest matters.

OEP's new structure will address the growing volume and complexity of managing CDER's executive programs. OEP maintains all the executive functions for the center – including learning and organizational development and advisory committee management. These changes will help us as a center to more effectively keep pace with scientific innovation and new program mandates – allowing us to more effectively accomplish our regulatory mission.

Office of Communications (OCOMM)

The Office of Communications provides a variety of services to fulfill CDER's internal and external communications needs in support of the center's many programs and initiatives. OCOMM's organizational changes are administrative in nature. The changes include establishing three branches within the existing Division of Drug Information and renaming two divisions to better reflect their expanded mission. The Division of Health Communications will become the Division of Public Education and Outreach, and the Division of Online Communications will become the Division of Digital and Online Communication.

Moving Forward

The finalized reorganization announced today reflects our commitment to ensuring that FDA and CDER are in the best position to meet the needs of a growing organization with expanding authorities.

I want to thank those involved with this extensive effort, particularly Edwin Echegoyen, acting director of the Office of Management, and his staff. I truly appreciate their diligent work and valuable input as they helped us reach another important milestone in CDER history.

Janet Woodcock