MEMORANDUM

Date: September 6, 2013

From: Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

To: Members of the Program Alignment Group

Bernadette Dunham, Director of Center for Veterinary Medicine
Michael Landa, Director of Center for Food Safety and Applied Nutrition
Karen Midthun, Director of Center for Biologics Evaluation and Research
Melinda Plaisier, Associate Commissioner for Regulatory Affairs
Jeffrey Shuren, Director of Center for Devices and Radiological Health
Steven Solomon, Acting Deputy Associate Commissioner for Regulatory Affairs
John Taylor, Acting Deputy Commissioner for Global Regulatory Operations and Policy
Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine
Janet Woodcock, Director of Center for Drug Evaluation and Research
Mitchell Zeller, Director of Center for Tobacco Products

cc: Lisa Barclay, Chief of Staff
Walter Harris, Deputy Commissioner for Operations

Subject: Directorate/ORA/Centers Coordination and Program Alignment

Background

In recent years, FDA has experienced unparalleled challenges posed by globalization, scientific innovation, and the increasing breadth and complexity of the products it regulates. In addition, FDA's regulatory authority and mandates have expanded through groundbreaking legislation such as the Family Smoking Prevention and Tobacco Control Act, the Food Safety Modernization Act, the Affordable Care Act, the Food and Drug Administration Safety and Innovation Act, the Generic Drug User Fees Amendments of 2012, the Animal Drug User Fee Act, and the Animal Generic Drug User Fee Act. These challenges, authorities, and mandates have significant implications for FDA's operations, and the strategic relationship between the Directorates, ORA, and the Centers.

The Assignment

To best adapt to these developments and to effectuate the steps required to successfully address these changes, I am charging the Program Alignment Group (the Acting Deputy Commissioner for Global Regulatory Operations and Policy, the Deputy Commissioner for Foods

and Veterinary Medicine, the Associate Commissioner for Regulatory Affairs and Acting Deputy, and the Center Directors) to identify and develop plans to modify Agency functions and processes in order to best achieve mission-critical Agency objectives. The work that FDA must accomplish requires the combined efforts and commitment of the offices and programs across the Agency. Therefore, it is imperative that there be greater clarity and transparency about relative roles and responsibilities of the Directorates, ORA, and the Centers, as well as greater operational and program alignment among these organizations that avoids duplication of function and effort, if FDA is going to succeed in the future.

More specifically, we need to transition to distinct commodity-based and vertically-integrated regulatory programs with well-defined leads, coherent policy and strategy development, well-designed and coordinated implementation, and a de-layered management structure. This move towards a specialized program-based model will take time and a level of organizational change across both the Centers and ORA. Implementing this vision of vertical integration and streamlining of management and decision making will require discussion in the near term regarding roles and responsibilities, metrics and accountability, and decision rights.

I charge you to start working on a core set of operational changes that are necessary to achieve optimal alignment between the Directorates, Centers, and ORA. These initial areas include, but are not limited to:

- Specialization, to the extent that it has not been achieved, across FDA's inspection and compliance functions, that enables the Agency to mirror, adapt to, and track the continuing program-based specialization within FDA's regulated industries and the demands of new legislation;
- Training that is developed collaboratively by ORA and the Centers and leads to the development of competency requirements, training curricula, certification/ qualification/accreditation processes, performance assessments, and a continuing education program that enables FDA to enhance and maintain its world-class workforce;
- New work planning that improves FDA's selection of firms, inspection frequency, and compliance efforts that is based on risk factors, public health outcomes, past inspectional history, and operational experience, and that is reported through performance-based metrics clearly demonstrating public health and compliance outcomes;
- Compliance policy and enforcement strategies that are clear, current, outcome-based, and effectively communicated in order to maximize FDA's ability to protect public health and to exercise effective and efficient industry oversight;
- Laboratory optimization that increases specialization; fosters program alignment and collaboration between the Directorates, ORA, and the Centers; and enhances efficiency within the current laboratory configuration; and
- Center and ORA practices, processes, and resources that are effectively aligned in order to support ORA's implementation of FDA's commodity-based and prevention-focused regulatory programs.

To successfully implement these initial changes will take time, commitment, continued investment and evaluation, unity, and my support. Therefore, I am requesting that you work collectively to further define and implement these changes. Please report back to me within the next three months on your plans, including timing, for addressing these issues.

As with any organization that is implementing fundamental change, we need to continuously evaluate and improve our processes, management, and structure. I appreciate your willingness to work together to address the changes necessary to move FDA into the future as a modern and globalized public health-regulatory Agency, and I look forward to periodic updates as these processes, plans, and concepts are developed.