MEMORANDUM

February 3, 2014

TO: Bernadette Dunham, Director, Center for Veterinary Medicine (CVM)
Michael Landa, Director, Center for Food Safety and Applied Nutrition (CFSAN)
Karen Midthun, Director, Center for Biologics Evaluation and Research (CBER)
Melinda Plaisier, Associate Commissioner, Office of Regulatory Affairs (ORA)
Jeffrey Shuren, Director, Center for Devices and Radiological Health (CDRH)
Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy (GO)
Steven Solomon, Acting Deputy Associate Commissioner, Office of Regulatory Affairs (ORA)
Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine (OFVM)
Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER)
Mitch Zeller, Director, Center for Tobacco Products (CTP)

cc: Lisa Barclay, Chief of Staff
Elizabeth Dickinson, Chief Counsel
Walter Harris, Deputy Commissioner for Operations/Chief Operating Officer

FROM: Margaret A. Hamburg, Commissioner of Food and Drugs

SUBJECT: Program Alignment Group Recommendations - DECISION

Introduction

On September 6, 2013, I charged this group with identifying and developing plans to modify Agency functions and processes to best achieve mission-critical Agency objectives. I have reviewed the results of your extensive consideration of the relative roles and responsibilities of the Directorates, the Centers and the Office of Regulatory Affairs (ORA) as well as the need for greater operational and program alignment among these organizations in response to my charge. I want to thank you all for the time and effort that you have invested in this initiative and for your many fine ideas. With this memorandum, I intend to chart a course for modifying Agency functions and processes to improve communication and collaboration and to clarify roles, responsibilities and decision rights across all Agency components.

First, let me echo some key themes that I have heard from many of you during this process:

- Our responsibilities are changing rapidly, forcing us to work in fundamentally new ways and to be as technologically up-to-date as possible.
- The work that FDA must accomplish requires the combined efforts and commitment of the offices and programs across the Agency.

- FDA needs to transition to distinct commodity-based (e.g., drugs, medical devices, foods) 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 toward a specialized program-based model will take time and a level of organizational change across both the Centers/Directorates and ORA. Implementing this vision of vertical integration and streamlining management structures and decision-making processes will require further discussion and delineation in the near term regarding roles and responsibilities, metrics and accountability, and decision rights.

Decisions for Implementation

In response to my September 6 memorandum, you have reached a common set of recommendations that will achieve the goals of improving communication and collaboration and clarifying roles, responsibilities and decision rights across all Agency components. As a result, I have made several decisions regarding a core set of operational changes. Based on your input, and where appropriate at this time, I have designated leads for certain compliance and enforcement-related activities, with the expectation that additional discussion among the affected parties will be warranted on several critical issues, as discussed more fully below.

- **Commodity-Based and Vertically-Integrated Regulatory Programs** – First and foremost, you have unanimously recommended that our regulatory and compliance activities be organized around distinct commodity-based and vertically-integrated regulatory programs. Those would include:

    1) Pharmaceutical quality (includes drugs and biologics regulated by CDER and veterinary drugs)
    2) Food and feeds
    3) Medical devices and radiological health
    4) Products regulated by CBER
    5) Tobacco
    6) Bioresearch Monitoring (BIMO)

    These programs should have governance and budgets that ensure that resources are allocated and devoted to strategic priorities and goals and that FDA speaks with one voice on policies and operations related to any given commodity. It is important to note that ORA will be more fully aligned with the Centers, but will not be diminished organizationally, operationally, or fiscally.

- **Specialization** – I charged you with identifying how specialization could be achieved across FDA's inspection and compliance functions in order to enable the Agency to mirror, adapt to, and effectively oversee the rapid technical advancements and specialization within FDA's regulated industries and the demands of new legislation. The impetus for change comes from a host of forces that affect FDA and places even greater demands on ORA and the Centers, including the increasing diversity and complexity of manufacturing operations, fueled in part by advances in science and the

increasing pace of innovation. Indeed, some medical devices are so complex that we may need sub-specialists trained in just a segment of that industry in order to carry out effective oversight of a manufacturer. Such realities lead to the need for commodity-based employees, including investigators, compliance officers, import reviewers, laboratory personnel, and managers, and they should be centrally managed in ORA commodity-specific offices that coordinate closely with the Centers and Directorates. One area, the Bioresearch Monitoring (BIMO) program, would be a shared responsibility of the relevant Centers, ORA and the Agency Office of Good Clinical Practice.

I want to emphasize the need to specialize not only the inspection force and laboratories by commodity-based regulatory programs, but also the compliance officers who manage the results of investigations. The goal should be to have a cadre of compliance officers across the Agency who have a similar level of technical expertise as the specialized investigators and who can work more closely with Center experts on complex scientific, manufacturing, or other regulatory challenges.

- **Training** - A critical component of our move toward specialization will be our ability to train to the necessary levels of scientific or technical competence. I charged you with considering training that is developed collaboratively by ORA and the Centers and that leads to the development of an agreed-upon commodity-based set of competency requirements, training curricula, certification/qualification/accreditation processes, performance assessments, and a continuing education program that enables FDA to enhance and maintain a world-class workforce. You have agreed with that concept.

  To implement it, we should maintain ORA's current training infrastructure ("ORA University"), while ensuring active engagement and collaboration with technical experts in the Centers on curricula, trainer qualifications, and other elements of a successful training program. Implicit in this, of course, is the understanding that Center management will designate and support staff resources to assist with curriculum development and other essential training elements and will provide ORA with the guidance that it needs for successful training in any given specialty area. A further goal must be the assurance that all specialists in ORA and the Centers that perform compliance activities, including investigators and compliance officers, are trained in the same operational procedures so that regulated industry experiences uniform, consistent application of our regulatory standards.

- **Agency Work Planning** – I charged you with constructing a new program-based work planning regime that improves FDA's targeting and utilization of compliance-related resources 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. The work plan must also provide a multi-year outlook on future priorities and activities, thus allowing ORA and the Centers to adjust their resources to meet future program needs.

  I hereby direct the Centers/Directorates and ORA to oversee the development of each program's annual work plan, following the September 6 charge for a new planning

regime. In the future, the work plan will be considered as a mutual obligation by each party, and any deviation from the work plan should be only with mutual concurrence (with some leeway provided for emergencies, as determined by the Associate Commissioner for Regulatory Affairs (ACRA)). The Centers and ORA will share responsibility for monitoring adherence to the work plan on a regular basis and will engage in regular communication and coordination to ensure that the work plan is accomplished.

- **Compliance Policy and Enforcement Strategy** – You were asked to ensure that there are clear, current, outcome-based, and effectively communicated compliance policies and enforcement strategies. While specialization of compliance officers and staff should contribute to a greater efficiency and effectiveness in compliance, you have identified other barriers to efficiency, such as many layers of case review, inadequate coordination, and lack of prioritization. The answer, as you have suggested, is to establish firm lead roles that will diminish fragmentation of authority.

  Therefore, I confirm your recommendation that the Centers are responsible for leading the development and communication of compliance policy and enforcement strategies, in partnership and consultation with ORA. ORA will take the lead on execution of both compliance policies and enforcement strategies, in partnership and consultation with the Centers/Directorates. ORA and the Centers will have shared responsibility for internally communicating compliance policy and enforcement strategies.

  I am directing the Center compliance offices in consultation with ORA to identify specific policy needs, including any Compliance Programs or Compliance Policy Guides that should be established or updated, as well as a timeline for when such updates will be completed. As part of that guidance, each Center will work with ORA on establishing performance-based metrics for compliance casework and other actions. I believe that this level of clarification and identification of lead roles will produce the necessary collaboration and role identification that you are seeking.

- **Imports**- As with the compliance policy issues, there is a need for more specialization and better communication and coordination between the Centers and the field in the area of imports. ORA will work with the Centers to establish import strategies by commodity/product and will conduct import operations consistent with Center/Directorate risk-informed compliance strategies and policies. The Centers must provide specific prioritization for imports through the annual work plan based on the public health and compliance risk posed.

- **Laboratory Optimization** – You have identified laboratory optimization as an Agency priority, and you have also recommended increased specialization in this area. I agree and hereby direct that ORA and the Centers develop a plan that increases laboratory specialization, fosters program alignment and collaboration between the Directorates, ORA and the Centers, and enhances our capabilities and promotes efficiency within the current laboratory configuration. ORA labs will ultimately report centrally to a senior executive level scientist leading the Office of Regulatory Science within ORA and the

laboratories. The Centers and Directorates will collaborate with ORA labs to set strategic priorities.

- **Delayering** –ORA and the Centers should de-layer management and review levels, where feasible, in order to better enable FDA to take timely and appropriate action, avoid duplication, improve efficiency, and enhance accountability. Specialized units in ORA operating in program-based staffs will be directed and managed by commodity-specific offices and led by a senior executive. The ORA structure will evolve over time from the current geographically-based model to a program-based or functional model. I therefore am directing the Deputy Commissioner for Global Regulatory Operations and Policy and the Associate Commissioner for Regulatory Affairs to develop a plan and report back to me by June 1, 2014.

Next Steps

The decisions that I am making today do not address the many details that will need to be worked out to implement this new course. For example, we must decide with more specificity the extent and pace of specialization by commodity across the Agency. I therefore ask that these next steps be considered by each of the Center Directors, the Deputy Commissioners for GO and OFVM, and the ACRA (or their respective designees) and that working groups of these key participants establish an Action Plan for each program that would define with greater specificity the operational changes and decisions described in this memo, as well as the processes for their implementation. The goal would be to have all Action Plans finalized and in place no later than October 1, 2014 as we begin the next fiscal year. Of course, if areas of disagreement emerge, I will be available for involvement as you request.

The specific areas that should be covered by each Action Plan are:

- Further clarification of roles and responsibilities of ORA and Centers/Directorates;
- Clarification of processes for budget formulation and execution, including decision rights. ORA will retain its own budget authority, and I direct the ACRA and Center Directors/Deputy Commissioners for GO and OFVM to work together to establish strategic priorities for resource allocation through the work planning process;
- Resource allocation and tracking;
- Plans for the pace and staging of the organizational change process;
- Joint development of commodity-specific work plans;
- Specific plans for transitioning inspection and compliance resources within ORA to commodity-specific structures;
- Plans for how import screening strategies, policies and decision-making will be executed, as well as clarification of the roles and relationships between the Centers/Directorates and ORA with regard to import alerts;
- Transition plans for lab specialization;
- Plans for the pace and staging of how compliance programs and policy guides will be assessed, updated and rolled out, including deadlines for completion;
- Identification and resolution of IT program support issues;
- Processes for commodity-specific policy development; and

- Plans to improve the training process, including adjustments related to content, frequency and target audience.

It will be important that we notify and explain these decisions to all employees in consultation with our union colleagues. I will ask Walter Harris and Lisa Barclay to make the necessary arrangements to ensure that the required notifications and consultations occur before these decisions are finalized.

Successful implementation of these changes will take time, commitment, continued investment and evaluation. Above all, we will need to maintain unity as an Agency.

Thank you again for your devotion to this effort. I believe that the time that you invested was well spent, and I applaud you for reaching consensus on so many challenging issues. I strongly believe that together we will make fundamental changes in how we perform the work of this Agency in ways that will enhance our ability to protect and promote the public health.

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