



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 26, 2007

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20515

Dear Mr. Chairman:

In light of your longstanding interest in the work of the Food and Drug Administration (FDA), I am writing to inform you of the FDA's proposal to reorganize its Office of Regulatory Affairs (ORA). Although this proposal does not involve a reduction in force, it does involve moving certain personnel and functions from one area of the country to another.

I know that you share my view that the FDA's effectiveness is critical to all Americans, and that is why it is essential that the agency put in place the programs and processes that will enable FDA to focus on doing the right things in the right ways to most effectively protect and advance public health. I am committed to making certain that FDA has efficient, modern performance-based tools and techniques, and that the agency is structured in a way that effectively supports state-of-the-art regulatory oversight.

ORA serves as FDA's public health presence across the country. They are the staff responsible for conducting inspections, collecting samples, analyzing those samples in ORA's network of testing labs, and taking enforcement actions.

As a part of my effort to ensure that FDA is prepared to meet both today's and tomorrow's challenges, I directed ORA to critically review their portfolio of responsibilities and resources. This review included considering changes to operating procedures and organizational structure that would position ORA to meet emerging 21st Century challenges. As part of their response to my request, ORA identified the need to change the organizational structure of ORA, including their laboratories.

The proposed organizational changes include strengthening six of ORA's regulatory laboratories by moving to these six laboratories the personnel, equipment and other resources from seven other existing labs. The seven labs are older facilities in need of costly renovations, or cannot expand to accommodate merging with another lab. These labs also have expiring leases and meet a range of other criteria which have lead FDA to consolidation in these areas. This transformation will allow ORA scientists to work more closely together and improve collaboration and synergy. This will allow us to invest in state-of-the-art equipment and processes in the remaining laboratories and to increase investment in other critical areas.

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Strengthening these six labs will help FDA better meet its mission to protect and promote the public health. Currently, FDA must pay the costs associated with approximately 40 percent more laboratory space than is needed to conduct the laboratory work to support all of FDA's field programs and activities. These six labs will accommodate and exceed the capacity of testing conducted in the existing 13 labs. Although today's ready availability of overnight delivery services diminishes the need for laboratories to be in close proximity to sample collection sites, the consolidated laboratories will be dispersed geographically. In addition, the six labs will continue to provide supporting layers of expertise with appropriate redundancies to protect against unforeseen operational problems, and surge capacity to deal with emergencies.

This proposed restructuring of ORA would begin in FY2008. Costs for the restructuring in FY 2008 are covered within the FY 2008 budget level. All analysts from closing labs will be offered jobs in the labs to which their work is transferred. We realize that some employees will not relocate and in order to retain as many as these valued employees as possible, we will seek to place them in other jobs in their current location. ORA needs to invest intellectual and financial capital in new approaches to emerging challenges such as the increasing complexity of the products and processes we regulate. ORA transformation provides an opportunity to staff teams of national experts in a variety of disciplines. Towards this end, the transformation plan provides for Centers of Excellence in those geographic regions of the country where labs will be closed.

As we work to refine and finalize this plan in the few weeks, we are eager to answer any questions and discuss this in greater detail with you or your staff, at your earliest convenience. ORA's transformation efforts are the result of thoughtful, meticulous planning and a reflection of FDA's desire to further promote and protect the public health far into the future. We intend to work collaboratively with interested Members of Congress, including responding to requests for additional information about our proposal. We are confident that, together, we will achieve our mutual goals of protecting the Nation's food supply and promoting the public health of its citizens.

I appreciate your continued interest in and support of FDA's activities. I have sent identical letters to the Chair and Ranking Member of FDA's authorization and appropriation committees in both chambers, as well as those who have written HHS or FDA on this important topic.

Sincerely,



Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Attachment

Attachment
Letter to Committee on Appropriations

ORA Transformation

6 Enhanced Laboratories:

- Northeast Regional Lab (Jamaica, NY)
- Southeast Regional Lab (Atlanta, GA)
- Arkansas Regional Lab (Jefferson, AR)
- Pacific Regional Lab Southwest (Irvine, CA)
- Pacific Regional Lab Northwest (Bothell, WA)
- Forensic Chemistry Center (Cincinnati, OH)

7 Closing Laboratories and Planned Opportunities for Excellence:

In the seven areas where there have been laboratories, FDA is planning on utilizing the significant expertise that already exists and focusing on the 21st Century challenges unique to each region. The ORA transformation provides the opportunity to serve these regions by establishing Hubs, Centers of Excellence, and other enhancements that capitalize on the resident expertise and needs, and benefit the Nation as a whole. By addressing the specific challenges that ORA is facing in each of these regions, FDA will be responding to the rapidly changing profile of the products it regulates. These regions, and the capability of the FDA employees who are stationed there, will continue to play a critical role in ensuring the safety of our Nation's food and drugs.

- Denver District Lab (Denver, CO)
- Detroit District Lab (Detroit, MI)
- Kansas City District Lab (Lenexa, KS)
- Philadelphia District Lab (Philadelphia, PA)
- San Francisco District Lab (Alameda, CA)
- San Juan District Lab (San Juan, PR)
- Winchester Engineering & Analytical Center (Winchester, MA)