

**Review of the FDA Office of Regulatory Affairs
(ORA)**

Report by the ORA Subcommittee to the FDA
Science Board
May 30, 2008

Background

- **March, 2006:** Science Board subcommittee charged to review scientific and technologic capacities required for the FDA mission
- **December, 2007:** findings and recommendations presented to the Science Board
- **ORA subcommittee formed:**
 - David R. Parkinson, Nodality Inc
 - Lonnie J. King, CDC
 - Cato T. Laurencin, University of Virginia
 - John A. Thomas, Indiana University School of Medicine

Review Process

- **Face to face meeting in Rockville 2/2008** with presentations by ORA staff
- **Teleconferences**
- **Visits to ORA regional offices and laboratories**
- **Review of FDA-provided information:**
 - Revitalizing ORA: Protecting the Public Health Together In a Changing World 1/2008
 - Action Plan for Import Safety 11/2007
 - FDA Strategic Plan
 - Food Protection Plan
 - ORA Prioritization Report Business Cases

General Findings and Recommendations of the Science Board Report, December 2007

- Serious scientific deficiencies in the Agency compromised its ability to meet current or emerging regulatory responsibilities
- Resourcing had not been increased in response to the increasing scope and complexity of the FDA mission
- Issues were identified with scientific organizational structure, the size and capability of the scientific workforce, and the informational technology infrastructure
- Beyond resource-related issues, organization and management of scientific endeavors was termed critical, and the Science Board called for a "phased approach based on a well thought-out plan"

The Unique Characteristics of ORA

- ORA is the inspection and enforcement arm of the FDA, with a broad mandate
- Attendant significant challenges of technology, management and communication
- In recent years: increase in quantity and complexity of workload, increase in legislative-mandated responsibilities, increase in public expectation
- Yet, until recently static or decreasing human and budgetary resources

Findings and Recommendations of the ORA Internal Process "Revitalizing ORA" January 2008

- "Revitalizing ORA" document represented an intense three month review process by >100 ORA and other FDA staff
- Activity linked with recent important mandates affecting ORA
- Characterization of changes in three areas:
 - (i) working environment: the effects of increasing globalization
 - (ii) workforce issues: new technologies, new skill sets
 - (iii) tool-related issues: IT and communications infrastructure
- Thirteen proposals developed for initial analysis, development, and implementation

District Office and Laboratory Visits, April 2008

- Human resource issues: static lab FTE resources, lack of science-based career path advancement
- Lack of enterprise software infrastructure to connect laboratory equipment
- Difficulties in new equipment procurement; incorporation of new technology to enable greater productivity
- Inefficient or absent processes, inadequate resources to validate new technologies for more efficient forensically-acceptable product analysis
- Limitations in ability to engage external consultants
- On the positive side.....
 - Excellence in training programs
 - Pride in mission, extensive collaborations, desire to innovate, enthusiasm for ORA Revitalization activity

June 2, 2008

Findings of the ORA Subcommittee

- Recognition of the dramatic escalation of the scope, scale and implications of the ORA mission, together with congressional and public expectation
- Documentation of the failure over time to commensurately increase resources and technology with mission scope
- Agreement that business process improvement must accompany any increase in resource
- Belief that the ORA Revitalization Report is an objective and transparent review of the current state of ORA; it represents a valid outline for business process improvement organizational change
- Recognition of hurdles to organizational change

June 2, 2008

Recommendations of the ORA Subcommittee

- Support for the ORA Revitalization activity
- Identification of the importance of unambiguous FDA leadership support for ORA change
- General support for the discipline of regulatory science
- Recognition that capacity is important but not everything
- Linkage of broad Science Board recommendations to proposed ORA Revitalization activities:
 - Addressing the gap in inspection resources, certification programs for foreign manufacturers, greater foreign inspection, improved risk-managed inspection procedures, improved technology assay procedures; greater consultative interactions with external experts (Recommendations 3.1.1, 4.1.1)
 - Program to manage "new science" (3.1.2)
 - A new FDA scientific organization (3.1.4)
 - Creating better career ladders for scientists (3.2.1)
 - Improving IT infrastructure (3.3.1-5)
 - Strengthening collaboration, "governing by network" (3.2.4)

June 2, 2008

Conclusions (1)

- The subcommittee recognizes the scope and importance of the work conducted by ORA, and the importance of scientific excellence and capacity in this work
- Many of the issues identified by the Science Board 12/2007 Report are relevant to ORA; in addition ORA has unique characteristics and challenges stemming from its broad mission
- The subcommittee acknowledges the organizational assessment and reorganizational vision recently produced by ORA, and believes that the Revitalization activities represent a path towards the scientific reinvention of ORA

Conclusions (2)

- The subcommittee recommends to the Science Board that FDA leadership be encouraged to resource and support the implementation of the prioritized Revitalization activities
- ORA is encouraged to report back to the Science Board at some appropriate time on the status of progress with this implementation
