Office of Regulatory Affairs
Report from the Field

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AFDO Annual Meeting
June 2009
Challenges & Response

• Globalization
• Workforce
• Performance Expectations
• Science & Laboratory Infrastructure
• Communication
• One ORA
Drivers

• Internal – ORA Revitalization

• External – Congressional Mandates
ORA Revitalization

Launched mid-2007 to meet new challenges. Goals:

• Ensure continuity of mission and leadership.

• Foster regulatory compliance throughout the life cycle of imported and domestic products.

• Enhance tools and scientific resources.

• Embed scientific risk based assessments and approaches.

• Encourage collaboration and leveraging to maximize regulatory impact.
Fundamentals

• **Environment** - ORA must regulate globally.

• **Workforce** - The “right people” in the “right places” with the right skill sets.

• **Tools** - Invest in information technology and communications infrastructure; state of the art laboratories and rapid screening tools; risk management capability; and all areas of mission support.
Congressional Mandates

- FY08 $150 million supplemental
- First significant increase in ORA resources in several years
- Increase for FY08 – FY09
- Mandates increased inspections
Globalization

• FDA Beyond Our Borders

• Increase/enhance international partnerships

• Foreign Inspection Dedicated Cadre

• Increase ORA’s participation in international activities
Workforce

• Hiring initiative

• Training and Retaining

• Succession Planning

• Infrastructure
Performance Expectations

• Expand & enhance capacity & capability
  – Field Force
    • New Hires & Training
    • New positions –
      – Emergency Response Coordinators (Regional & Districts)
      – Quality Managers (Regional & Districts)

• Increase partnerships with states
  – 50 State Initiative on Food Safety
  – Rapid Response Team Grants
  – Assess and enhance existing agreements
Science & Laboratory Infrastructure

Enhance & “modernize” field science
• Science Strategic Plan

• Analytical Tools Initiative

• Sample Management Initiative

• Strategic utilization of Mobile Labs

• Challenge Initiatives
Enhancing communication:

• Internal
  – Within FDA
  – Within ORA

• External
  – Local, State, Federal, and Foreign partners
One ORA

• Working as a single field organization

• Meeting Performance Goals nationally

• Senior Management Team

• RFDDs working as a team
Meeting the Challenges

• ↑ Budget and staff

• Enhancing infrastructure and culture

• ↑ Partnerships – domestic and foreign

• Revitalizing existing paradigms and operations to better meet current and future needs

• Focusing on the science and taking a life-cycle approach

• Embracing the globalization of our work
Questions?

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