

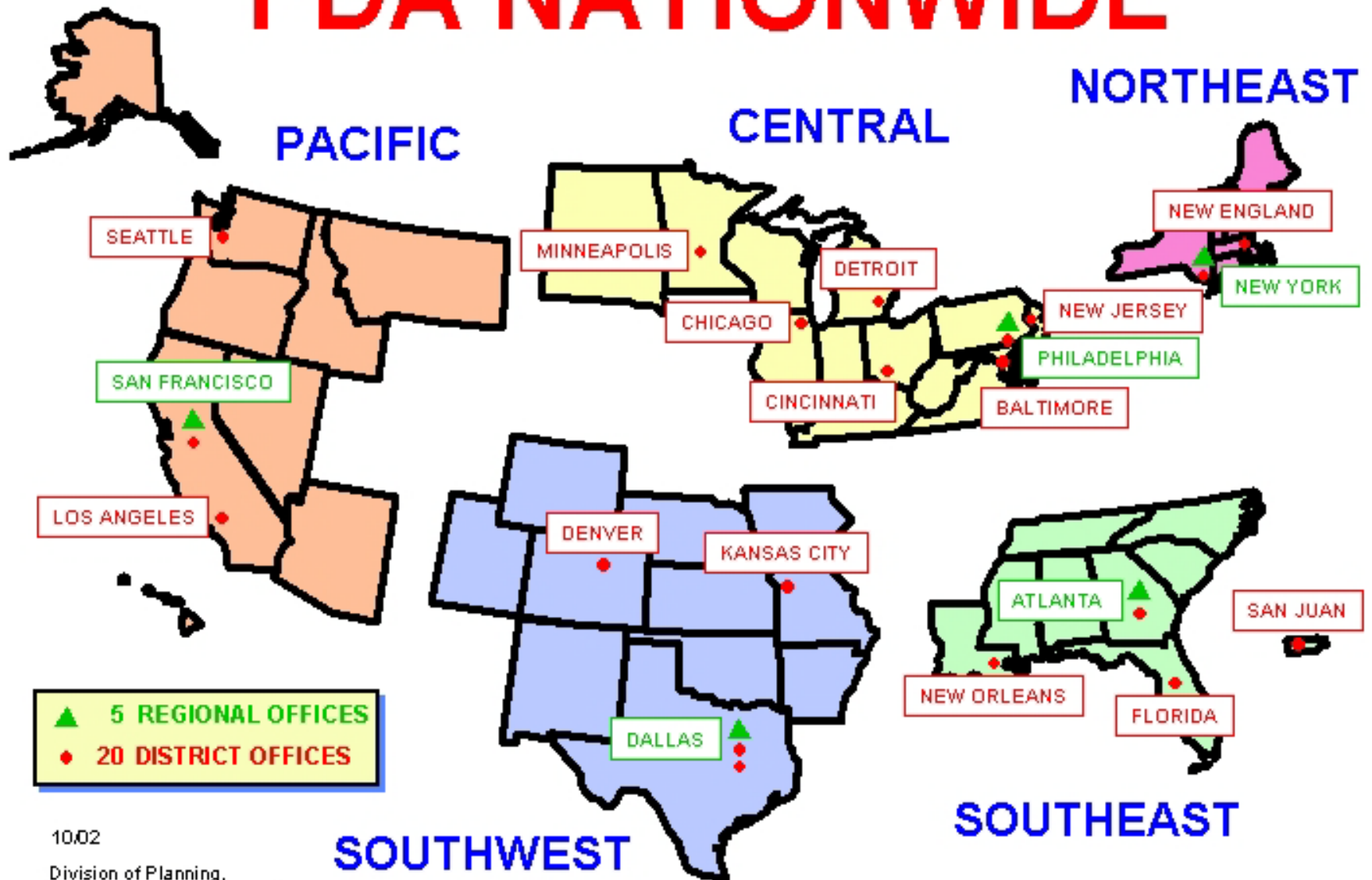


Office of Regulatory Affairs Report from the Field

Mrs. Melinda K. Plaisier
Regional Food and Drug Director
Central Region
U.S. Food and Drug Administration
U.S. Department of Health and Human Services

AFDO Annual Meeting
June 2009

FDA NATIONWIDE

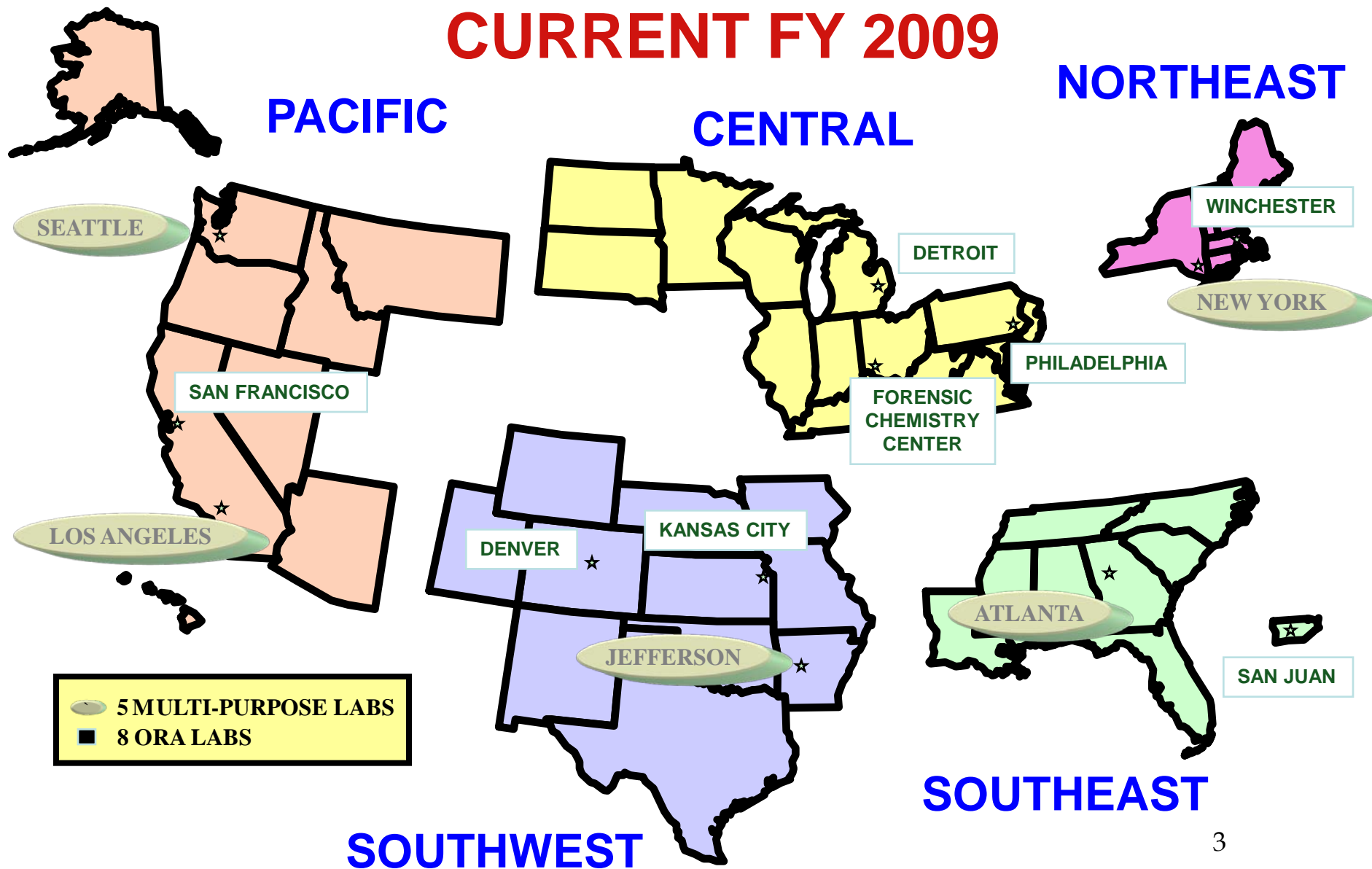


▲ 5 REGIONAL OFFICES
◆ 20 DISTRICT OFFICES

10.02
Division of Planning,
Evaluation, and Management



OFFICE OF REGULATORY AFFAIRS 13 FIELD LABORATORIES CURRENT FY 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

Communication

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?

Melinda.Plaisier@fda.hhs.gov

20 N. Michigan Avenue, Suite 510

Chicago, IL 60602

312-596-6501 (phone)

312-886-1682 (fax)

