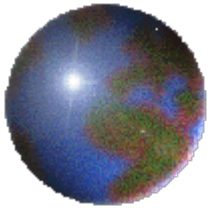
Report from the Field: Pathway to Global Product Quality and Safety



Melinda K. Plaisier
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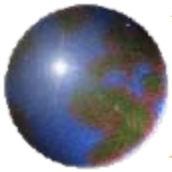
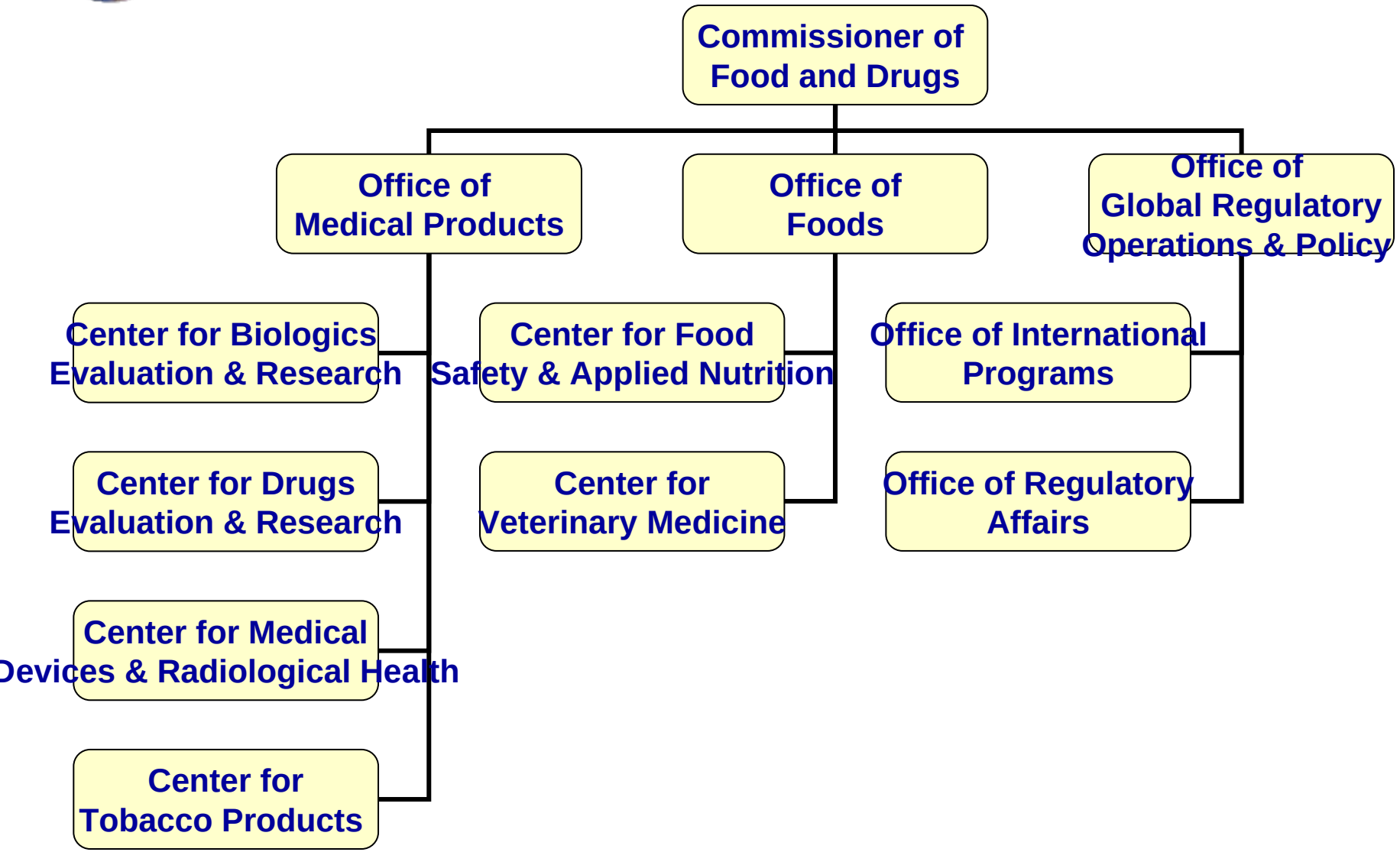
Office of Regulatory Affairs
Office of Global Regulatory Operations and Policy
U.S. Food and Drug Administration

Association of Food and Drug Officials
June 2012

“Leading the Way to Building Global Integrated Food, Drug and Medical Device Safety Systems”

- FDA Reorganization – Office of Global Regulatory Operations and Policy
- FDA Strategic Plan 2011 – 2015
- Pathway to Global Product Safety and Quality Report
- Advancing Regulatory Science at FDA
- Global Engagement Report
- ORA Investments

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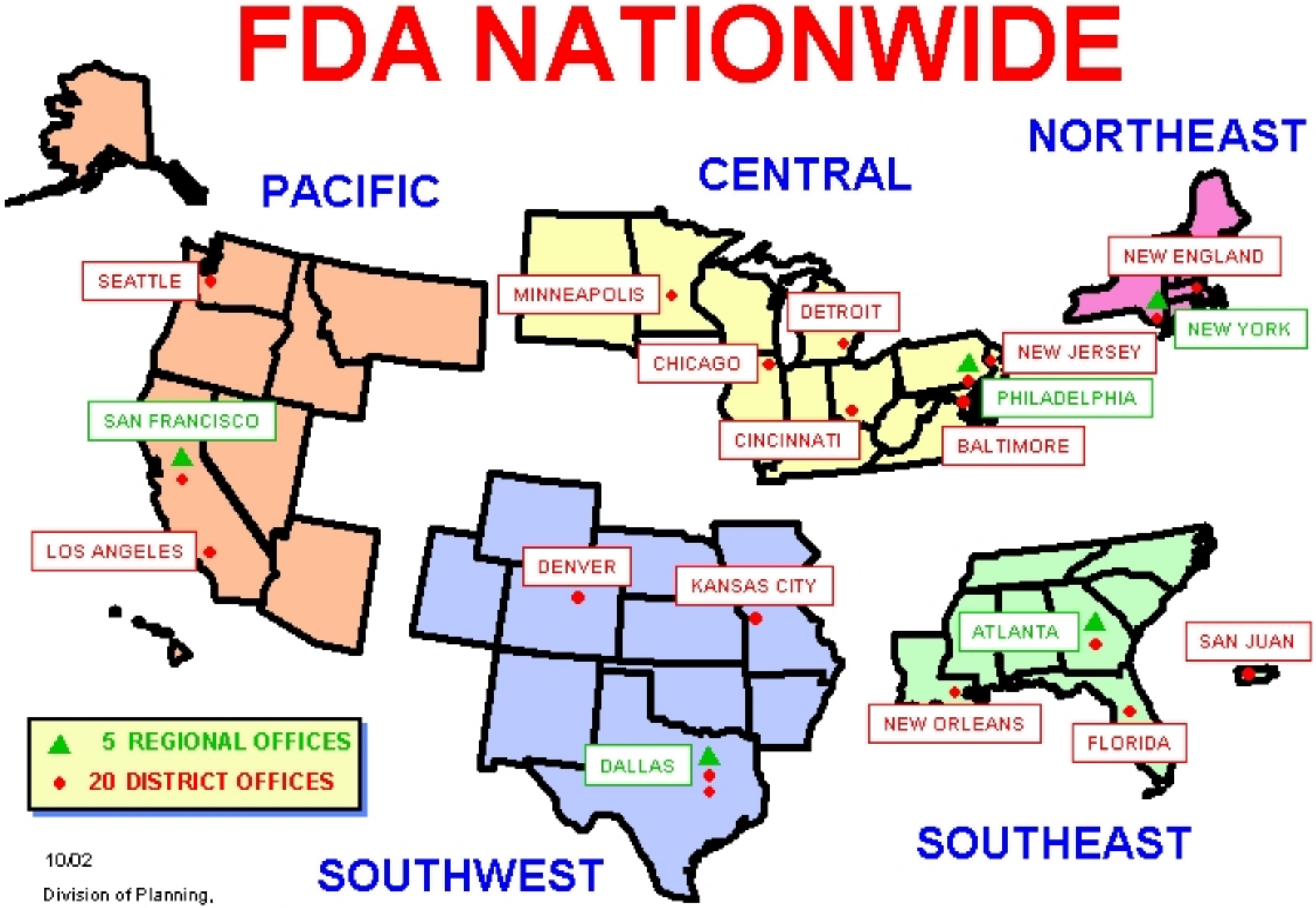
Office of Foods
Office of Global Regulatory Operations & Policy
Center for Biologics Evaluation & Research
Center for Food Safety & Applied Nutrition
Office of International Programs
Center for Drugs Evaluation & Research
Center for Veterinary Medicine
Office of Regulatory Affairs
Center for Medical Devices & Radiological Health
Center for Tobacco Products

About ORA

Enterprise Wide ~ One third of FDA

- Inspections
  - Pre-approval
  - Post market
- Investigations
  - Consumer Complaints
  - Emergency Response
  - Criminal Investigations
- Sample Collection and Analysis
- Import Product Review
  - Field Exams
  - Sampling
- Partners with Foreign, Federal, State, Local, Tribal and Territories
- Funds grants and cooperative agreements
- Provides technical assistance and training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DALLAS
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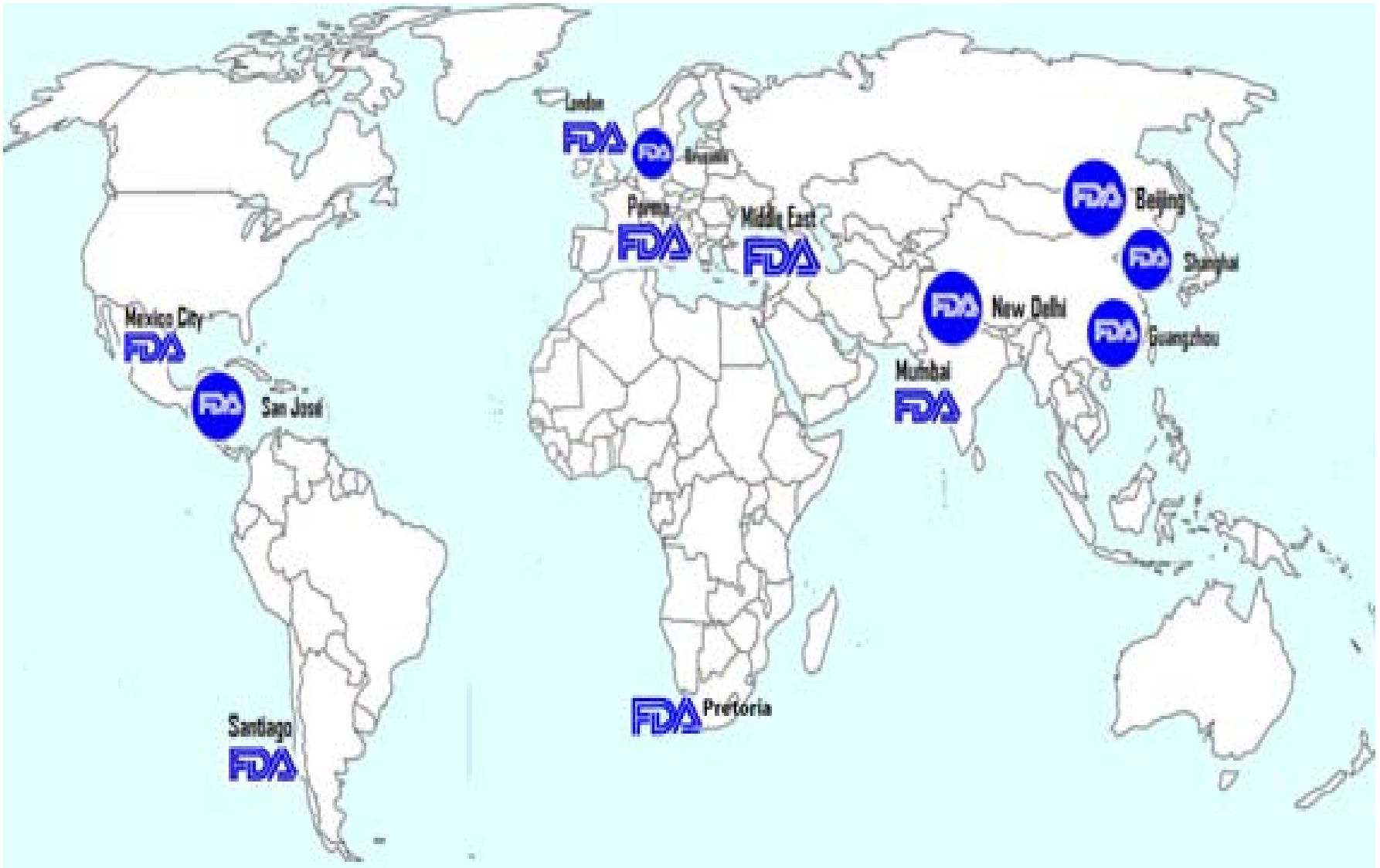
20 DISTRICT OFFICES
SOUTHWEST
SOUTHEAST
10/02
Division of Planning,
Evaluation, and Management

OFFICE OF REGULATORY AFFAIRS
13 FIELD LABORATORIES in FY 2010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FDA Strategic Priorities

Guiding Principles:

- **Science-based decision-making**
- **Innovation/collaboration**
- **Transparency**
- **Accountability**

FDA Strategic Priorities

- Advance Regulatory Science & Innovation
- Strengthen the Safety & Integrity of the Global Supply Chain
- Strengthen Compliance and Enforcement
- Expand efforts for Special Populations
- Advance Medical Countermeasures & Emergency Preparedness

Pathways to Global Product Safety and Quality Report

Four Pillars

1. **Global coalitions of regulators**
2. **Global data information system**
3. **Expanded IT capabilities – information gathering & risk analytics**
4. **Enhanced allocation of resources based on risk**

Advancing Regulatory Science

1. Modernize technology
2. Stimulate innovation in clinical evaluation & personalized medicine
3. Support new approaches to improve product manufacturing & quality
4. Ensure FDA readiness to evaluate emerging technology
5. Harness diverse data through information sciences
6. Implement a new prevention-focused food safety system
7. Facilitate development of medical countermeasures
8. Strengthen social and behavioral science

Strategies for Global Engagement

- International offices & posts
- Strengthening regulatory capacity building
- Harmonizing science-based standards
- Leveraging knowledge & resources
- Risk-based monitoring & inspection
- Global surveillance, preparedness, & response
- Advancing regulatory science

ORA Global Investments

- Global Harmonization Task Force
- International Conference on Harmonization
- Pharmaceutical Inspection Cooperation Scheme
- Codex Alimentarius
- Bilateral and multilateral collaboration
- Law Enforcement Collaborations
- Laboratory Collaborations

ORA Internal Investments

- Dedicated Foreign Inspection Cadres
- FDA Foreign Offices
- Extended Foreign Office Details
- PREDICT and other IT tools
- Strategic field assessment

Meeting the Challenge

- Advancing regulatory science
- Increasing partnerships – foreign, federal, state, local and tribal
- Developing new operational models
- Ensuring organizational readiness
- Embracing globalization

Questions?

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