



Office of Regulatory Affairs

Presentation to The Alliance for a Stronger FDA

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Associate Commissioner for Regulatory Affairs
July 26, 2011

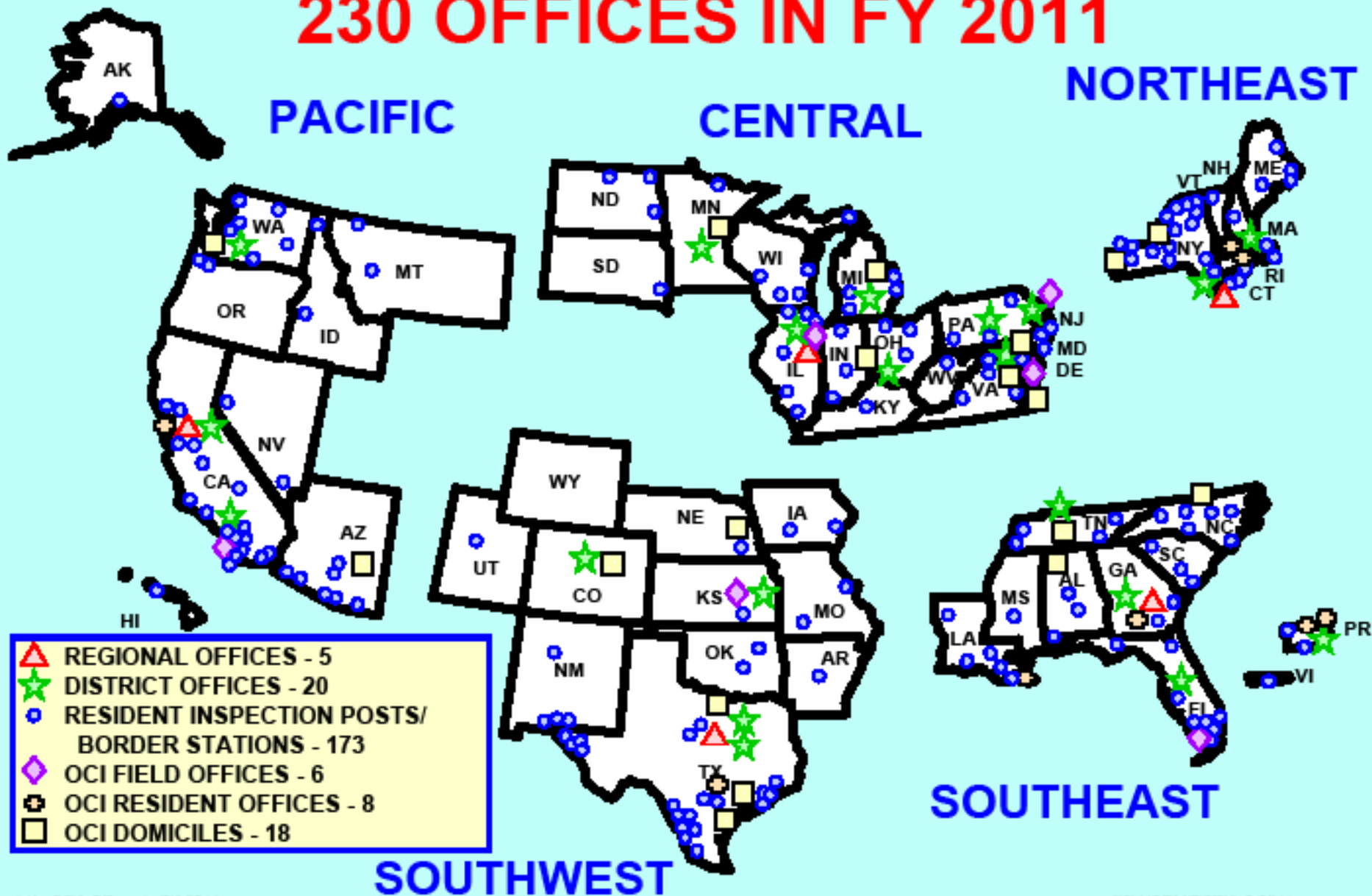


Overview

- About the Office of Regulatory Affairs (ORA)
- ORA's Strategic Priorities
- Commissioner's Reorganization – July 2011
- FY 2012 Budget
- Questions

OFFICE OF REGULATORY AFFAIRS

230 OFFICES IN FY 2011



About ORA

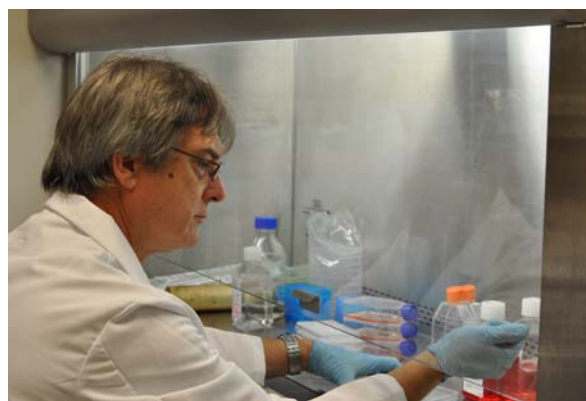
- Inspections
 - Pre-approval
 - Post market

- Sample Collection and Analysis

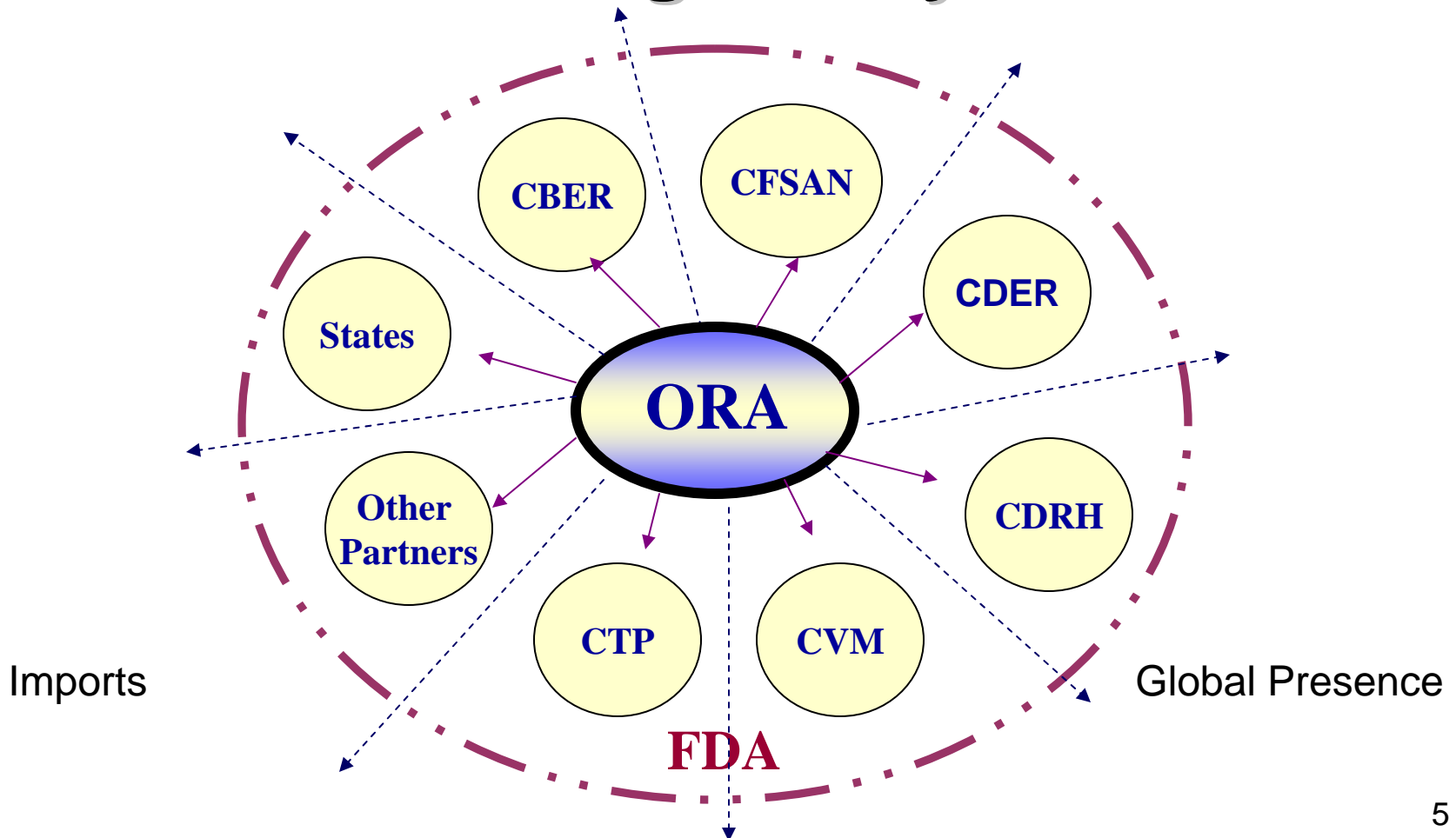
- Import Product Review
 - Field Exams
 - Sampling

- Investigations
 - Consumer Complaints
 - Emergency Response
 - Criminal Investigations

- Enforcement



Partnership with Product Centers and other Regulatory Partners



Globalization

- Globalization has fundamentally changed the environment for regulating food and medical products; it has created unique regulatory challenges:
 - Foreign inspections: increased demand
 - Comparability assessments
 - Counterfeiting
 - Foreign offices

Food Safety Modernization Act: Implementation

- Mandated inspection frequency
 - risk-based inspection frequency for domestic and foreign facilities
 - risk determination based on multiple factors
- New enforcement tools
 - mandatory recall
 - expanded records access
 - expanded administrative detention

Maintaining and Maximizing Efficiency of ORA's Inspectional Force

- With the FY 2008 Supplement, FY 2009 appropriation, and continued support in FY 10, ORA was able to increase its inspectional force by over 800 new investigators
- Greater specialization

Information Technology

- Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
- Screening tools for Investigators
- Handhelds

Enforcement

- Streamlined Review of Cases
- 5-year OAI Review
- Improved Recall Search Engine



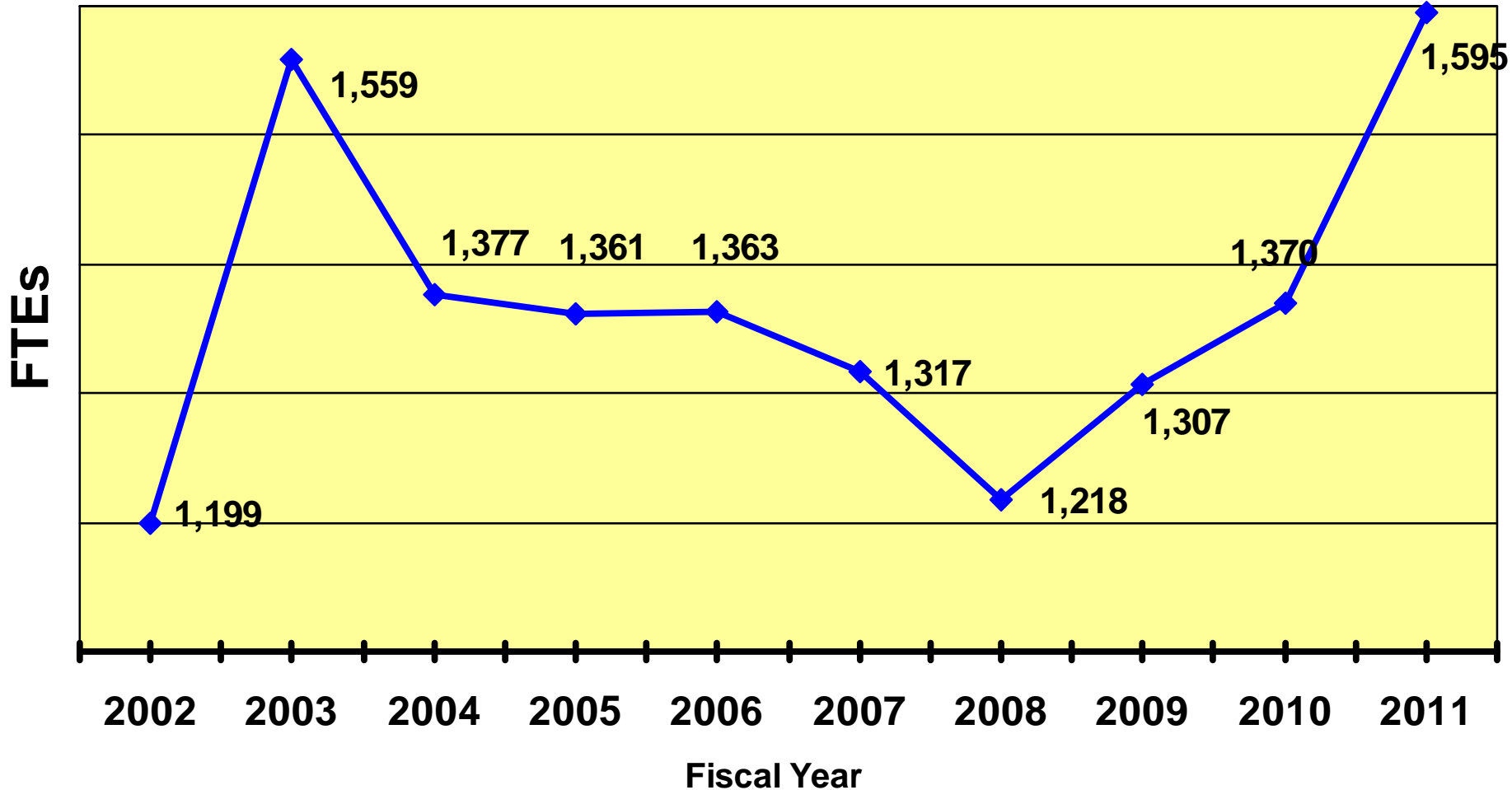
Commissioner's Reorganization - July 2011

FY 12 Budget

- President's Request:
 - increase of \$326.0 million for the Transforming Food Safety and Nutrition Initiative
 - increase of \$123.6 million for the Protecting Patients Initiative



FDA: Investigative FTE History





Questions?