Office of Regulatory Affairs

Presentation to
The Alliance for a Stronger FDA

Dara Corrigan
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
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

ORAs
CDER
CVM
CDRH
CFSAN
CTP
States
Other Partners
Imports
Global Presence
FDA
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

Fiscal Year

2002 2003 2004 2005 2006 2007 2008 2009 2010 2011

FTEs

1,199 1,377 1,361 1,363 1,317 1,307 1,218 1,370 1,595
Questions?