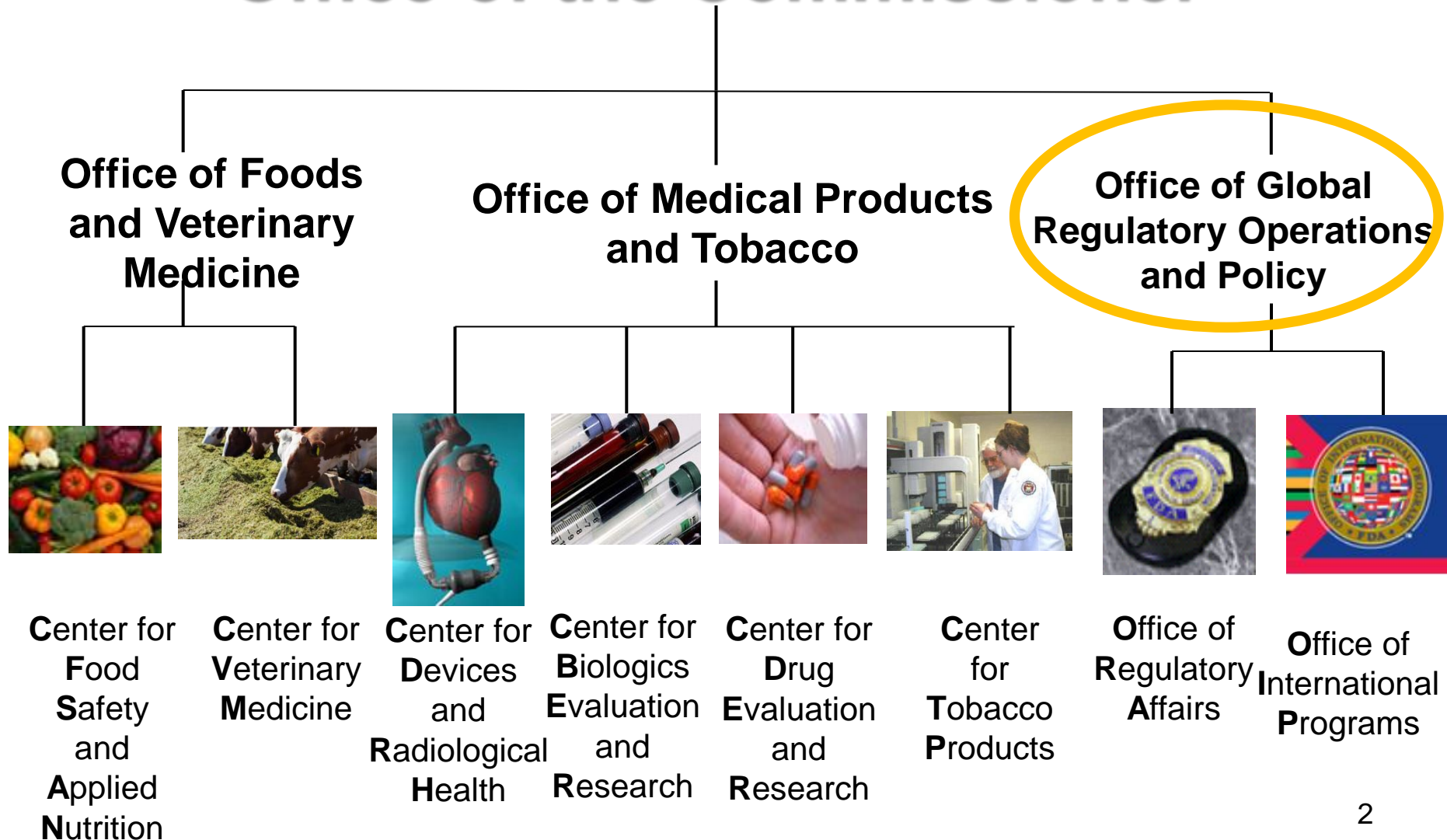


The Office of Regulatory Affairs (ORA) in a Global Environment: Complexity, Change, and Challenge

Alonza Cruse
Pharmaceutical Quality Program Director
June 27, 2016

Office of the Commissioner



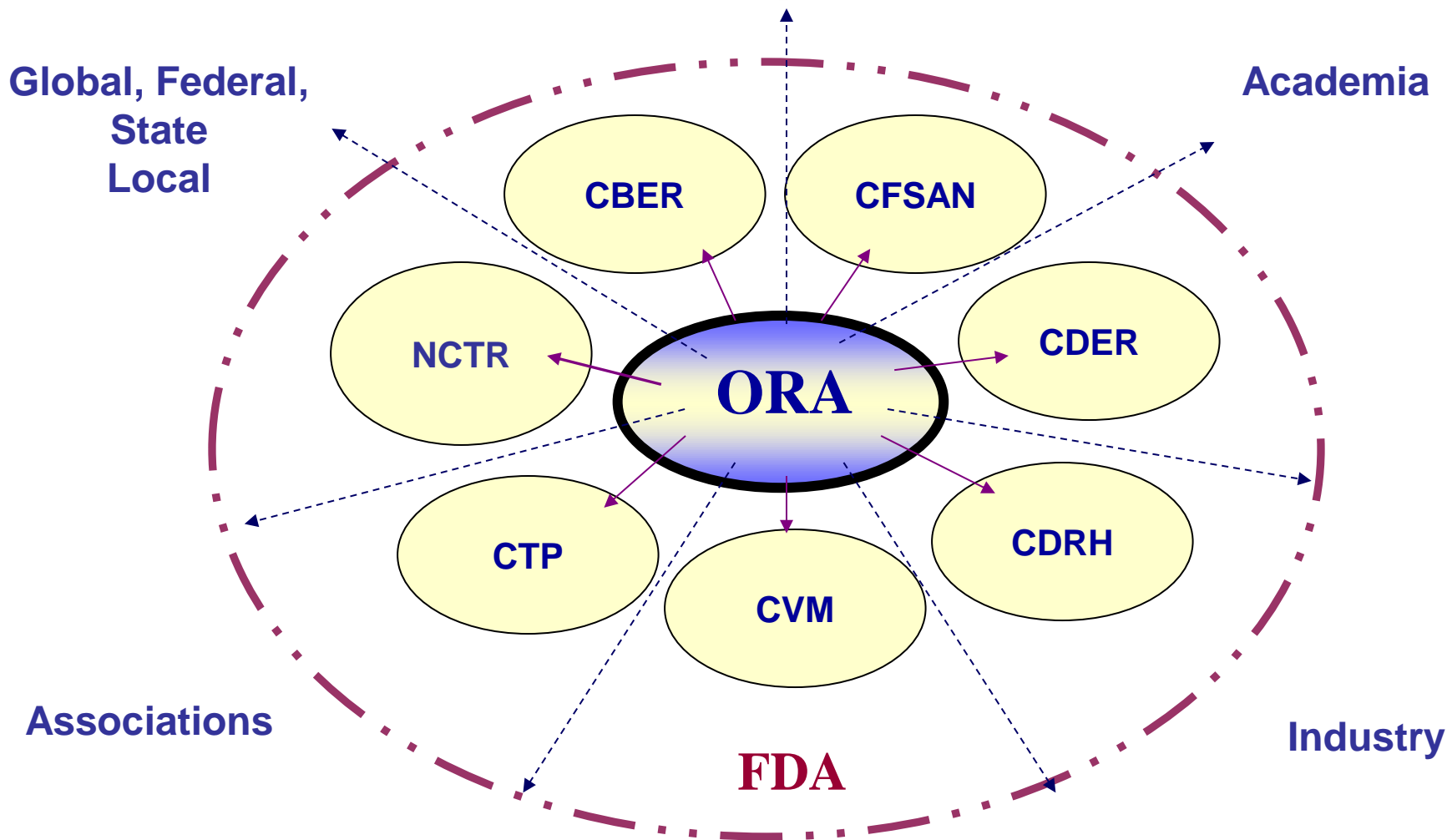
ORA: Profile

- ~5,000 staff: five regions, 20 districts, 6 OCI offices, resident posts and headquarters--over 227 locations
- staff covers domestic, imports and foreign inspection work
- investigators, including criminal investigators
- compliance officers
- 13 laboratories and the Office of Regulatory Science staffed with chemists, microbiologists, engineers, and other scientific disciplines
- state liaisons, state cooperative programs, the Office of Partnerships
- recall coordinators

ORA: Profile

- consumer complaint coordinators
- emergency response coordinators
- official establishment inventory coordinators
- quality system managers
- communications staff
- operational policy and risk management experts
- disclosure and FOIA experts
- training, education and development staff
- administrative and mission support staff

ORA Partnerships: How We Work



ORA: FY15 Scope of Work Snapshot

- >15,000 domestic inspections
- >3300 foreign inspections
- collected and analyzed >33,000 samples
- managed >34M import lines with >18,000 import refusals
- enrolled 51 new jurisdictions in retail food standards program
- managed ~\$72M portfolio of state contracts, grants and cooperative agreements
- 348 arrests and 305 convictions
- issued >17,000 WL (up considerably from FY14 due to increase in tobacco WL), without the tobacco increase, realized an increase of 133 across the other programs
- 1 seizure, 21 injunctions, and >9,000 recalled products
- contributed to or led work on 16 rules and 41 guidances for industry

Change

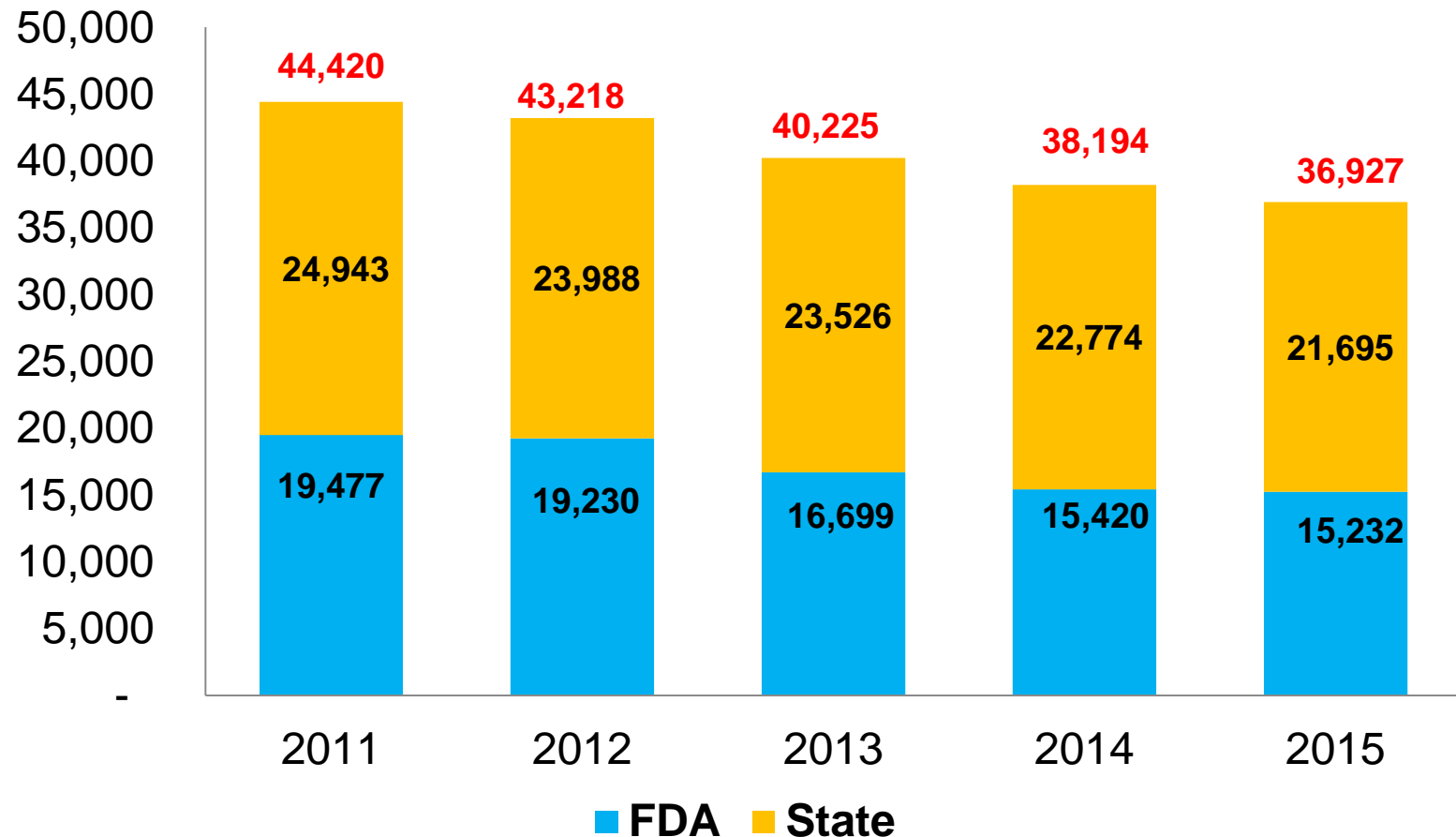
- Operational
 - Implementing Legislation
 - ORA Strategic Priorities
 - Center Initiatives
 - Program Alignment
- Organizational – Program Alignment
 - Commodity based and vertically integrated regulatory programs
 - Specialization
 - Training
 - Agency Work Planning
 - Compliance Policy and Enforcement Strategy
 - Imports
 - Laboratory Optimization
 - Delaying

Challenge: Globalization of Work

- Balancing organizational and operational change with shifts in work:
 - decrease in domestic inspections performed by FDA
 - increase in foreign inspections
 - increase in imports
 - increase in domestic investments and partnerships
 - shifting operations during significant organizational change

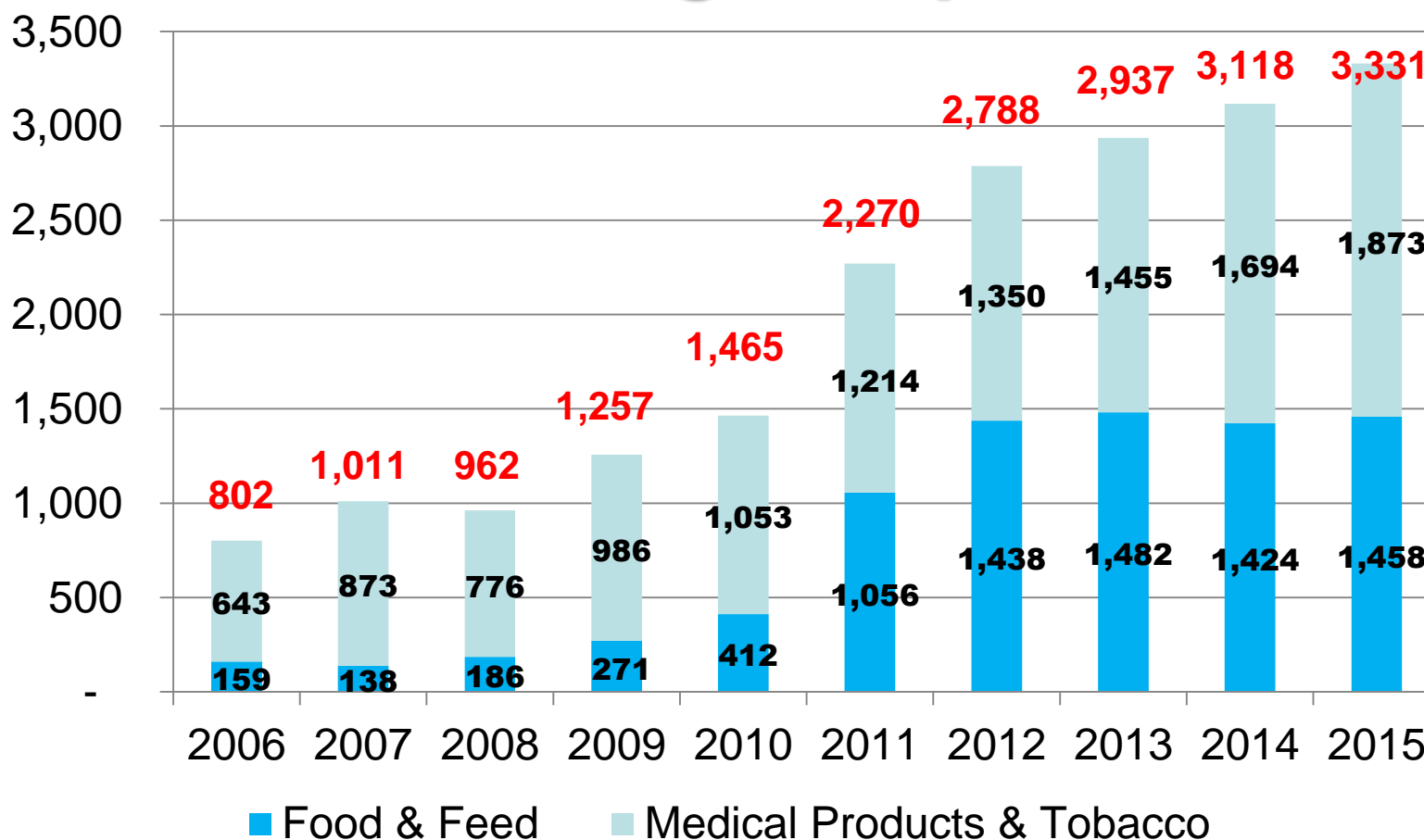


FDA Domestic Inspections



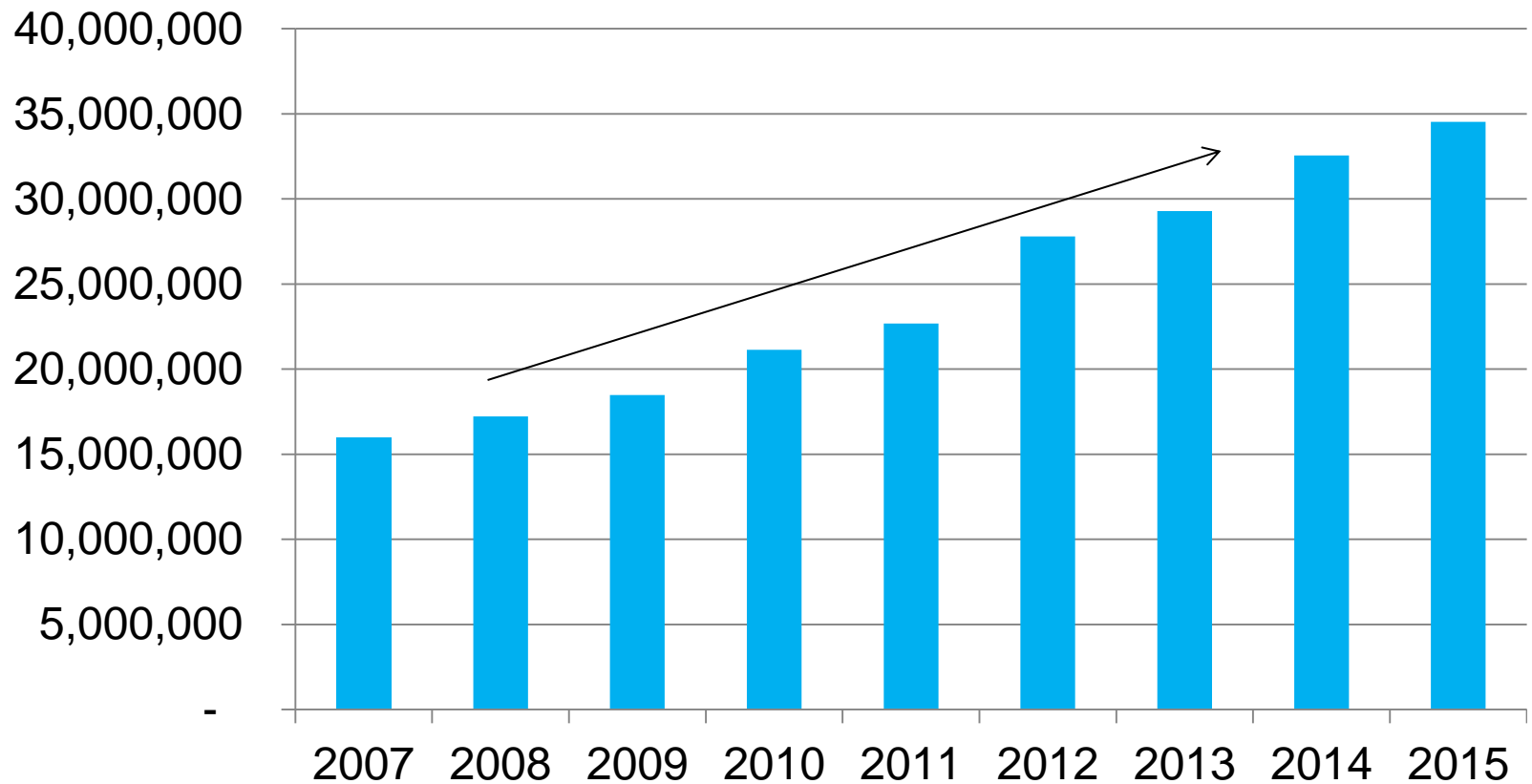


FDA Foreign Inspections



*ORA FY15 Data as of 12-10-15

FDA Import Lines



Meeting the Challenge

- Enhance the foreign inspection program
- Partner with OIP on foreign posts
- Leverage globally:
 - PIC/S and mutual reliance
 - Systems recognition, FSVP, VQIP
- Leverage domestically:
 - mutual reliance, Partnership for Food Protection, other critical collaborations, and cooperative agreements
 - import divisions

Looking Ahead

- New organizational and management models
- New operational tools
- Shifting focus from domestic to foreign
- Enhanced partnerships – domestic and foreign
- Opportunities for You



Questions?