FDLI

Enforcement, Litigation, and Compliance Conference

December 7-8, 2016
Washington, DC

ORA and FDA District Directors Forum

Steven B. Barber, Director, Cincinnati District Office, FDA

Douglas Stearn, Office of Enforcement and Import Operations, FDA

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2016 Compliance Update

Douglas Stearn

Director, Office of Enforcement and Import Operations
FDA Office of Regulatory Affairs

Topics to Include

- Program Alignment
- ORA Inspection Data
- Implementing Legislation and Agency Initiatives
- Compliance and Enforcement Statistics

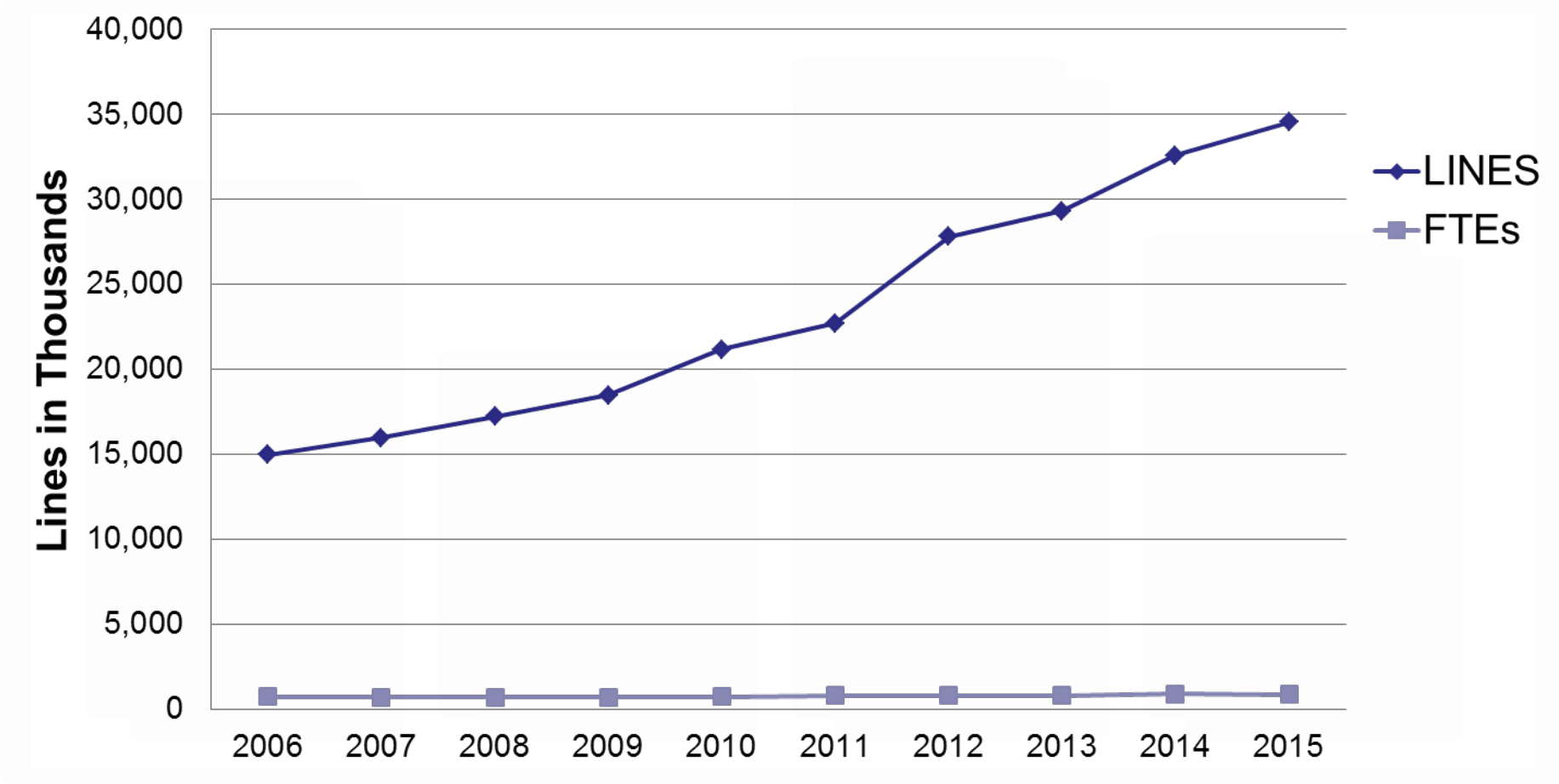
Program Alignment -- Goals

- Inspectorate specialized by program
- Expanded technical expertise
- Increased ability to keep pace with changes in manufacturing
- Goal of reduced timeframes for decision-making through both streamlining as well as team-based approaches

Program Alignment - Commitments

1. Establish Commodity-Based and Vertically Integrated Regulatory Programs
2. Increase Specialization
3. Enhance Training
4. Revamp Agency Work Planning
5. Improve Compliance Policy and Enforcement Strategies
6. Enhance Import Operations
7. Advance Lab Optimization
8. Address Delayering/Streamlining

Growth of FDA Imports

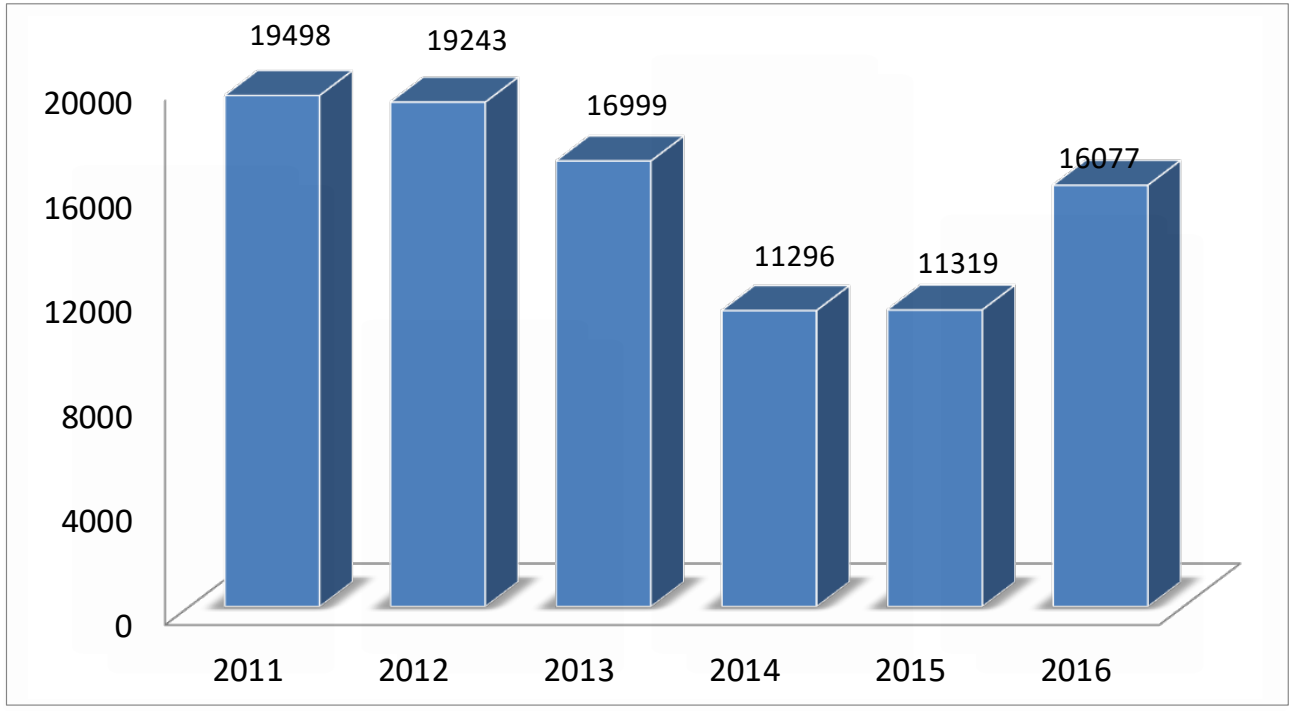


∗Lines are shipments of a certain type of product (i.e. if a container includes 1 million bottles of water and 5 million bottles of club soda, that would be one entry containing two lines).

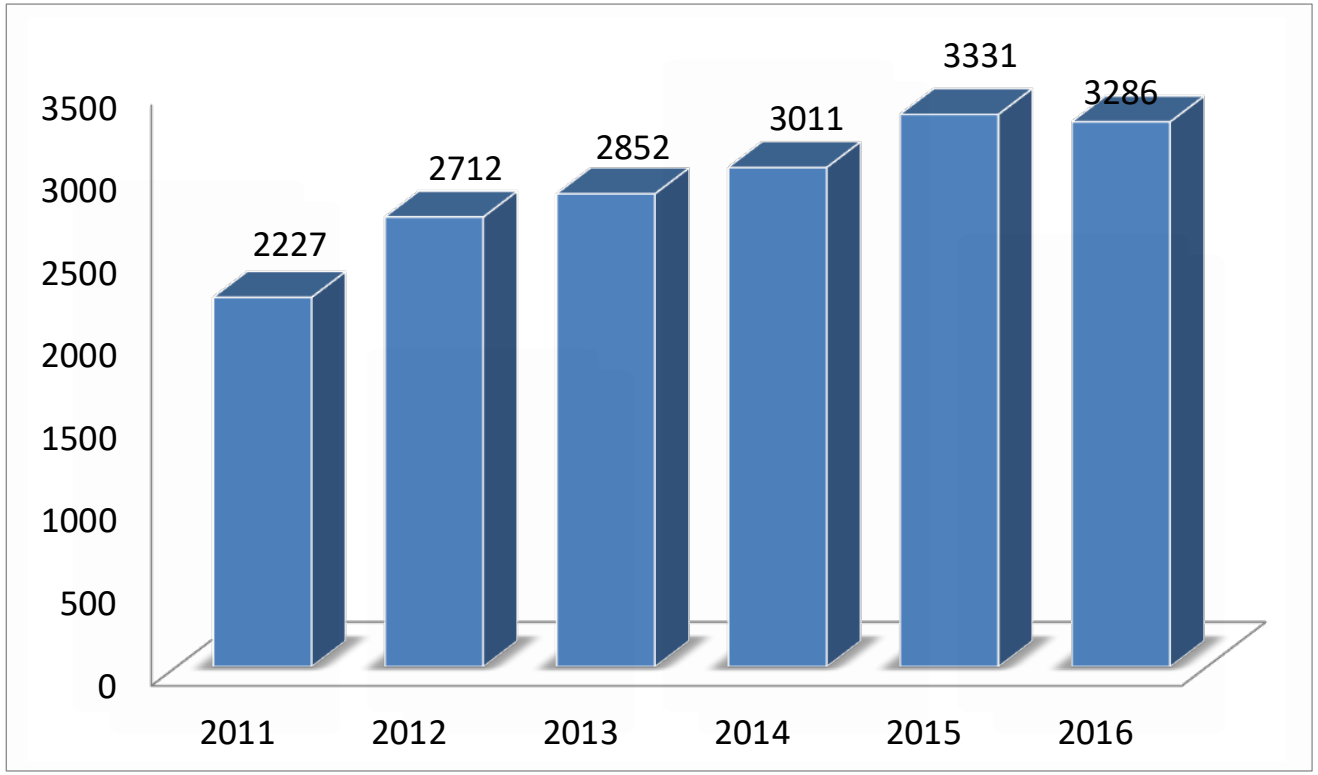
** FTEs contains both Import and Foreign planned FTEs

Domestic Inspections FY 2011-2016

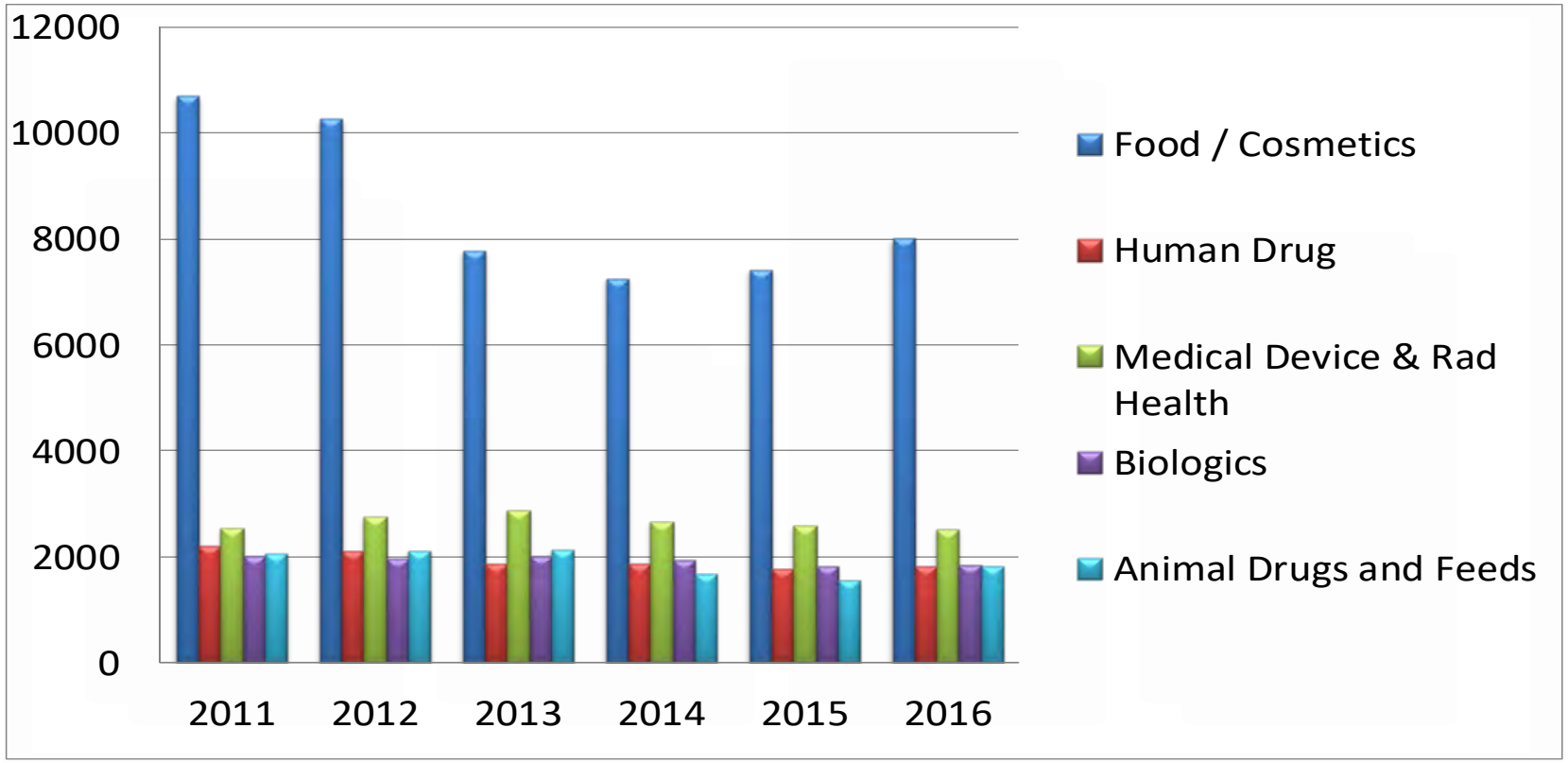
(All Commodities)



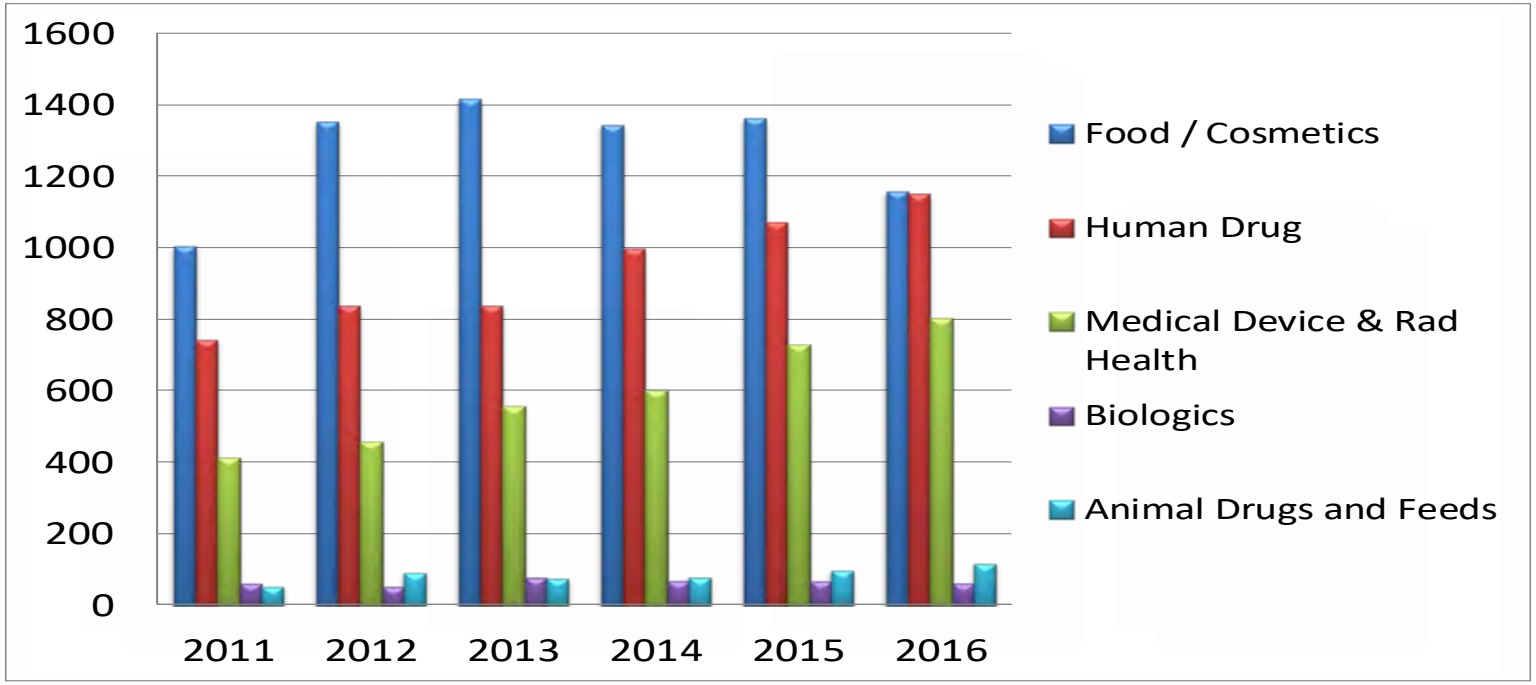
Foreign Inspections FY 2011-2016



Domestic Inspections by Program Area



Foreign Inspections by Program Area



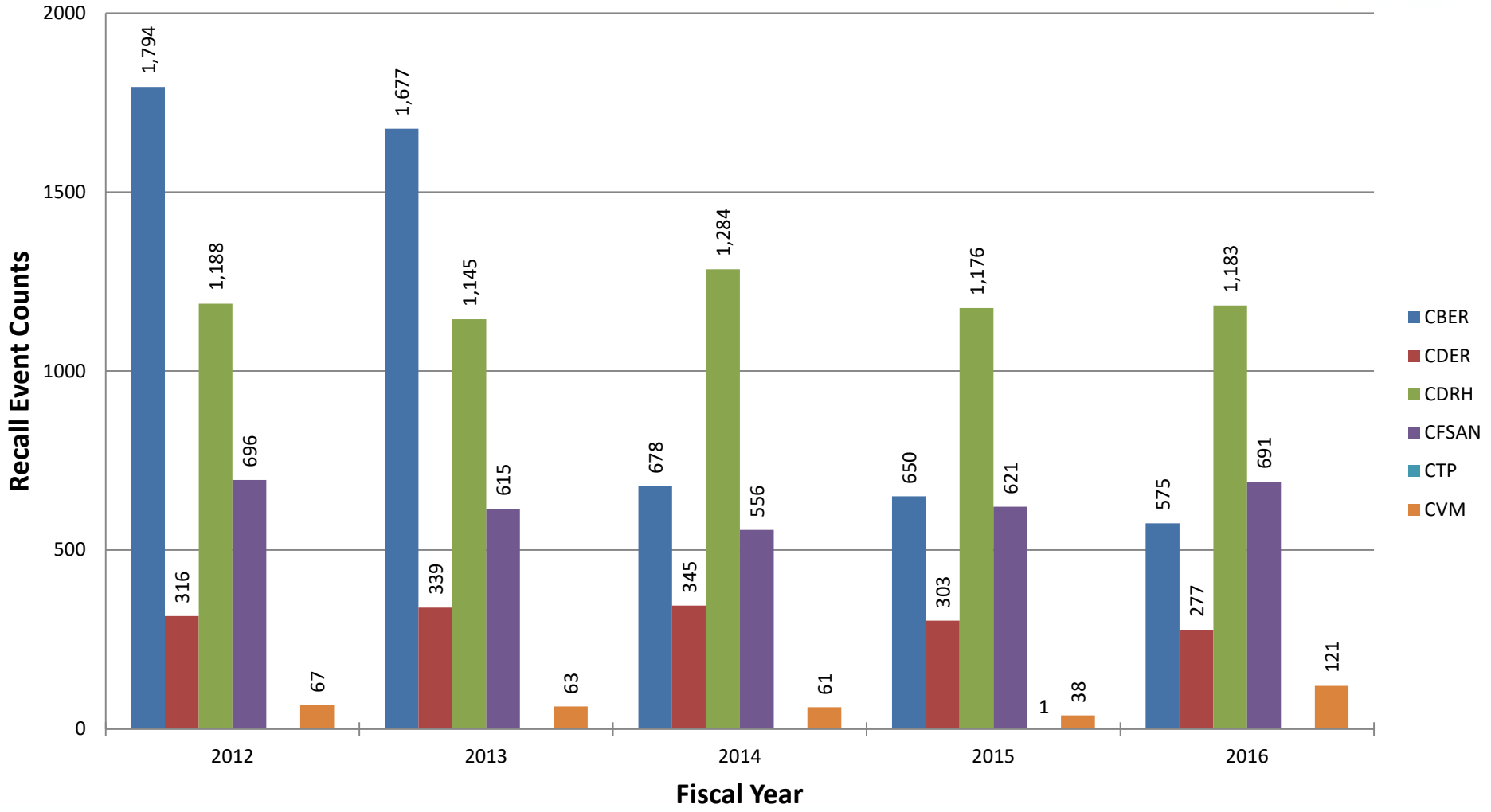
Regulatory Meetings and Enforcement

FY	Regulatory Meetings	Injunctions	Seizures	Debarments
2016	143	17	4	1
2015	138	21	1	17
2014	172	16	3	1
2013	170	19	3	8
2012	135	34	16	18
2011	118	33	11	15

Total Recalled Products for Class I & II by Center (2016 only)

	Class I	Class II	Total
CBER	1	513	514
CDER	108	1,272	1,380
CDRH	111	2,671	2,782
CFSAN	1,134	1,154	2,288
CTP	-	-	-
CVM	272	222	494
All Centers	1,626	5,832	7,458

Recall Event Counts by Program Area for Past 5 Fiscal Years



Implementation of Legislation

- FDASIA
  - GDUFA ramping up inspectional process and review
  - Records advance or in lieu of inspection (706)
  - Delaying, denying, limiting or refusing inspection (707)
  - Administrative destruction of imported drugs (708)
  - Administrative detention (709)
- FSMA: Rules on Preventative Controls, Produce Safety, Foreign Supplier Verification, Accredited Third Party Certification, Voluntary Qualified Import Program, Intentional Adulteration, and Sanitary Transportation
- Compounding Quality Act and Oversight

Thank you.

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

ORA Ombudsman

An Introduction

Jessica L. Zeller, J.D., M.A.

FDLI Conference

December 8, 2016

History and Objectives of Role

- Created in October 2015
- Facilitate informal and unbiased solutions for external parties' concerns
- Education – internal and external – needs/stress points of various parties

When to Use ORA Ombudsman

- Should come only after other avenues have failed

- Need an objective third party read
  - Can be confidential

In Practice…

- People actually use this service – including large and small companies, as well as individuals, consultants, lawyers, etc.
- There is *NOT* retribution for doing so – ORA wants to hear the problems

Examples

- Can’t get anyone to call you back/Don’t know who to call
- Question on next steps/expectations
- Confusion on imports
- Concerns about conduct of an investigator
- Confidential discussion needed

Contact

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www.fda.gov/ORAOmbudsman

U.S. FOOD & DRUG ADMINISTRATION

District Work Planning

Steven B. Barber
District Director
Cincinnati District

Surveillance vs. For Cause

- Surveillance
  - Risk Based
    - Each center has their own algorithm
  - Statutory obligations (i.e. FSMA)
- For Cause
  - Follow up
  - Recalls
  - Reports (FARs, Medwatch, Recalls, etc.)
  - Other

FSMA

- High Risk vs Non-high Risk
  - Known Safety Risk
  - Compliance History
  - Firm's Hazard Analysis & Controls
  - Intentional Adulteration/Certified Importer
  - Other

FSMA

- High Risk
  - Not less than once in 5 years since 2011
  - Not less than once every 3 years thereafter
- Non-high Risk
  - Not less than once in 7 years since 2011
  - Not less than once every 5 years there after

Contact

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