Office of Regulatory Affairs (ORA)

Office of Medical Device and Radiological Health

2023 Update

OMDRHO PROGRAM

OMDRHO KEY INITIATIVES AND PRIORITIES

-RETURN TO INSPECTIONS

- COLLABORATION & OUTREACH

Anne Reid, OMDRHO Program Director

April 2023

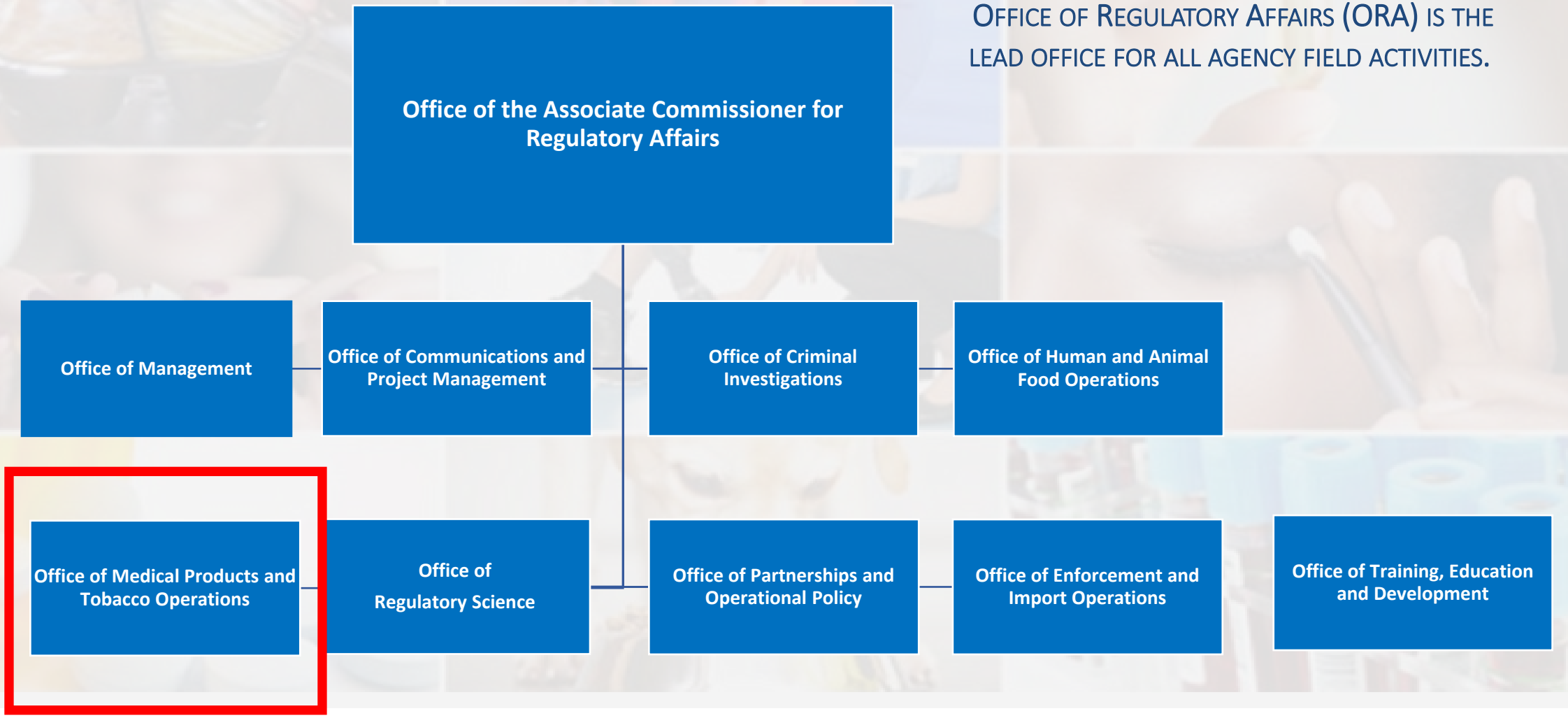
PROGRAM

OMDRHO

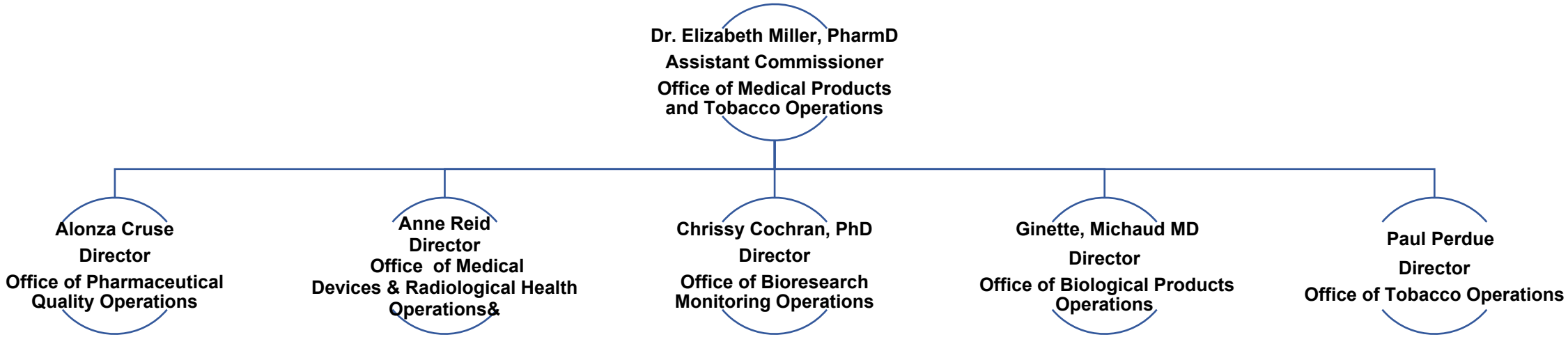
OMDRHO | Office of Medical Device and Radiological Health Operations

ORA Organization Chart

THE FDA'S OFFICE OF REGULATORY AFFAIRS (ORA) IS THE LEAD OFFICE FOR ALL AGENCY FIELD ACTIVITIES.



Office of Medical Products and Tobacco Operations



OMDRHO
Office of Medical Device and Radiological Health Operations

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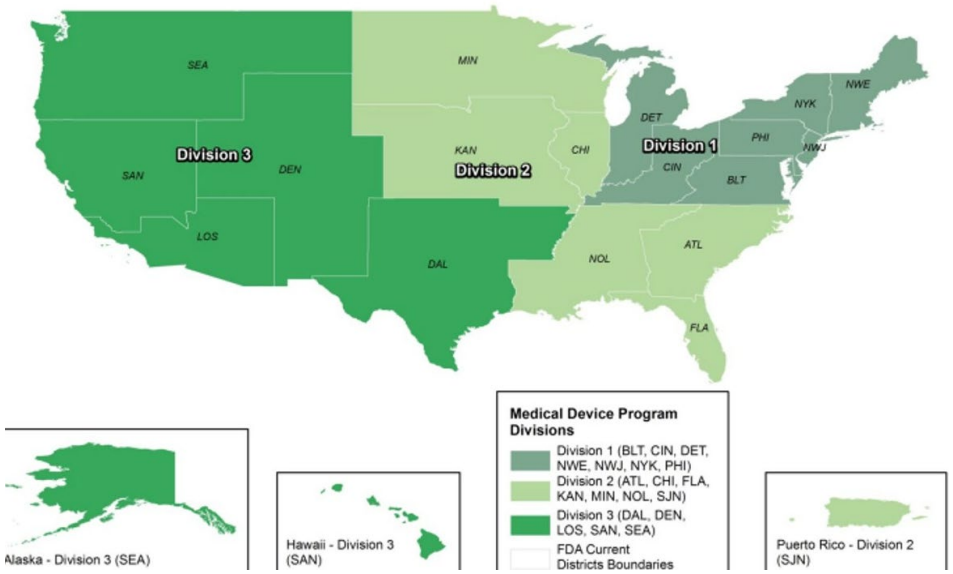


FY 23 Initiatives & Priorities

OMDRHO

Office of Medical Device & Radiological Health Operations (OMDRHO)

OMDRHO Vision: All patients, providers, and consumers are informed, protected, and have access to safe, reliable medical devices and radiological health products.

OMDRHO Mission: Protect and enhance public health by minimizing risk and by supporting access to safe, effective and quality medical devices and radiological health products.

FY 23 Key Priorities

All OMPTO Programs:

Enhance Investigator Preparedness

OMDRHO
- -Decrease new staff time from on-boarding to operational thru training
- -Enhance mid-career experience with Peer Pro Groups

Optimize Inspectional Processes

OMDRHO
- -Ensure global application of inspection priorities
- -Collaborate with CDRH on inspection considerations

Maximize our Tools for Regulatory Oversight

OMDRHO
- -Collaborate with CDRH on Recall Process Improvement
- -Improve use and enforcement of UDI
- -Join CDRH in one device oversight and total product lifecycle & Quality Compliance Action Team
- -Expand program outreach

FY23 OMDRHO Key Initiatives

WORKFORCE

- Inspectional guidance when encounter 510k concerns
- EUA resource summary for investigators

RISK MANAGEMENT

- Review post market signals by firm for follow-up needs
- RRA Process Improvements

PARTNERSHIPS

- PEAC
- MedCon
- OMDHRO Conference

-Supply chain/shortages

STRATEGIC DIRECTION

- One Medical Device and Radiological Health Program
- 820 Transition

Remote Regulatory Assessments

(RRA)

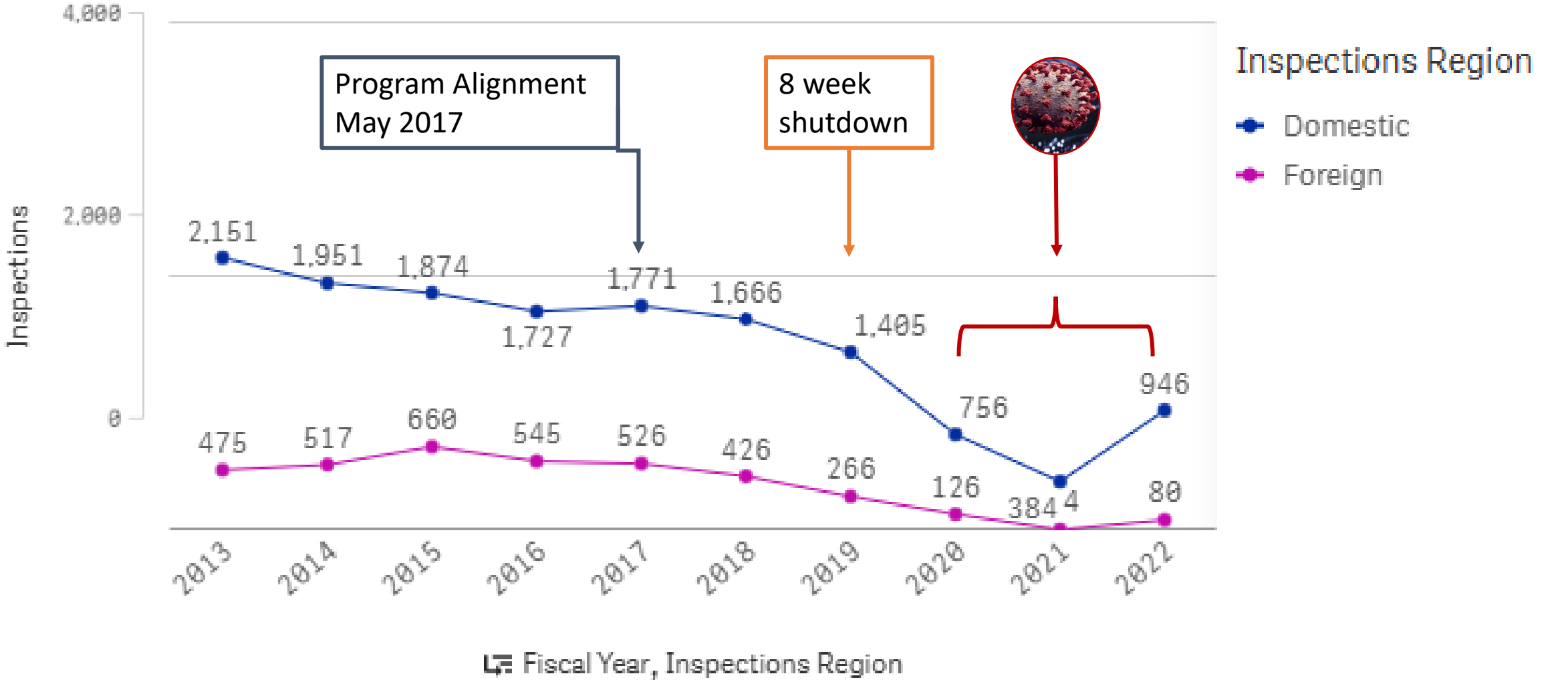
- Multi-Commodity- will continue to see use of this regulatory tool
- Remote, interactive engagement to review records firms are required to maintain
- Voluntary-no Form 483 Inspectional Observations
- Devices transitioning from voluntary to utilizing new authority

Return to Inspections

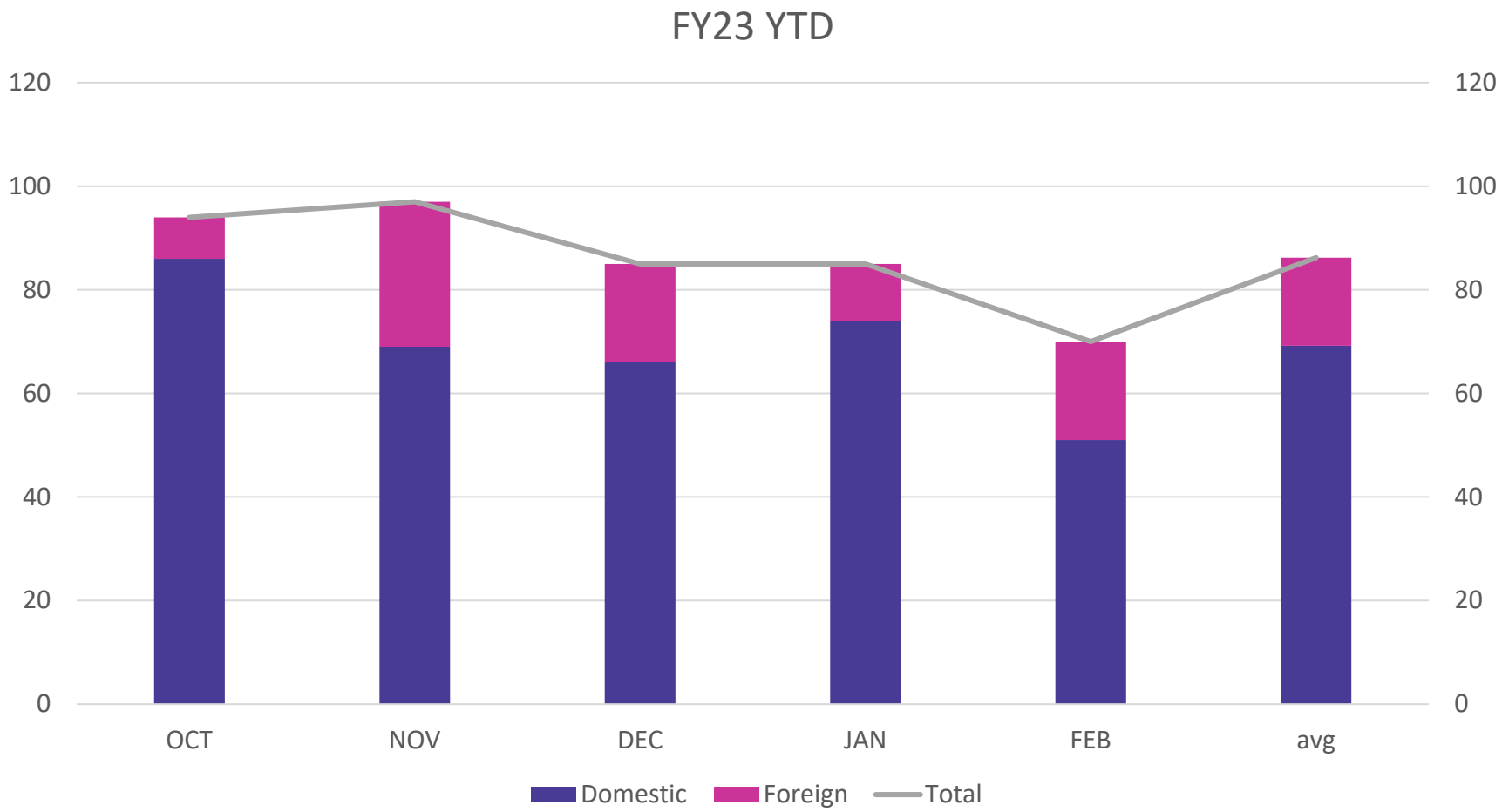
OMDRHO

Inspections by FY

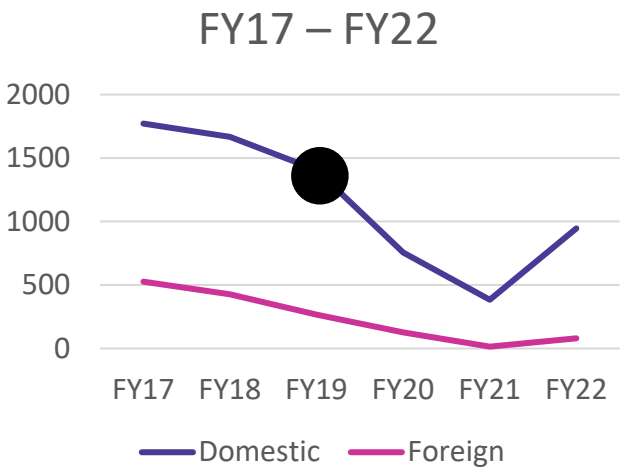
FDA U.S. FOOD & DRUG ADMINISTRATION
DATA DASHBOARD
Data Dashboard Home | Compliance Dashboards



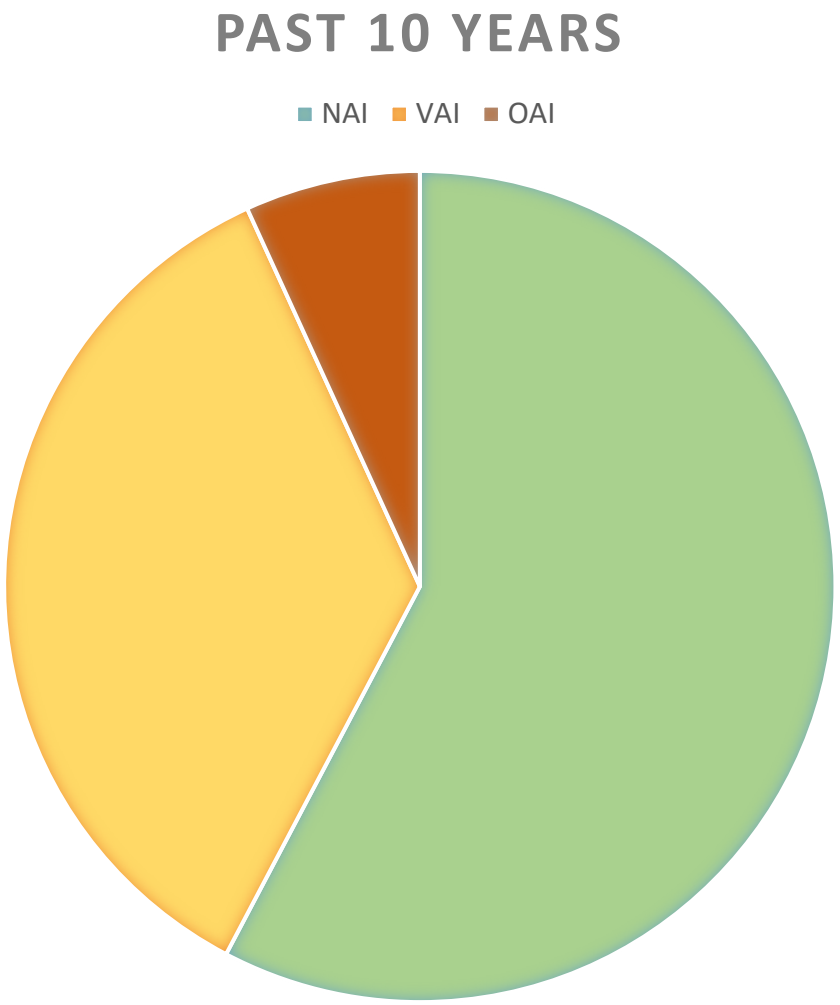
Inspections, FY17 - 22

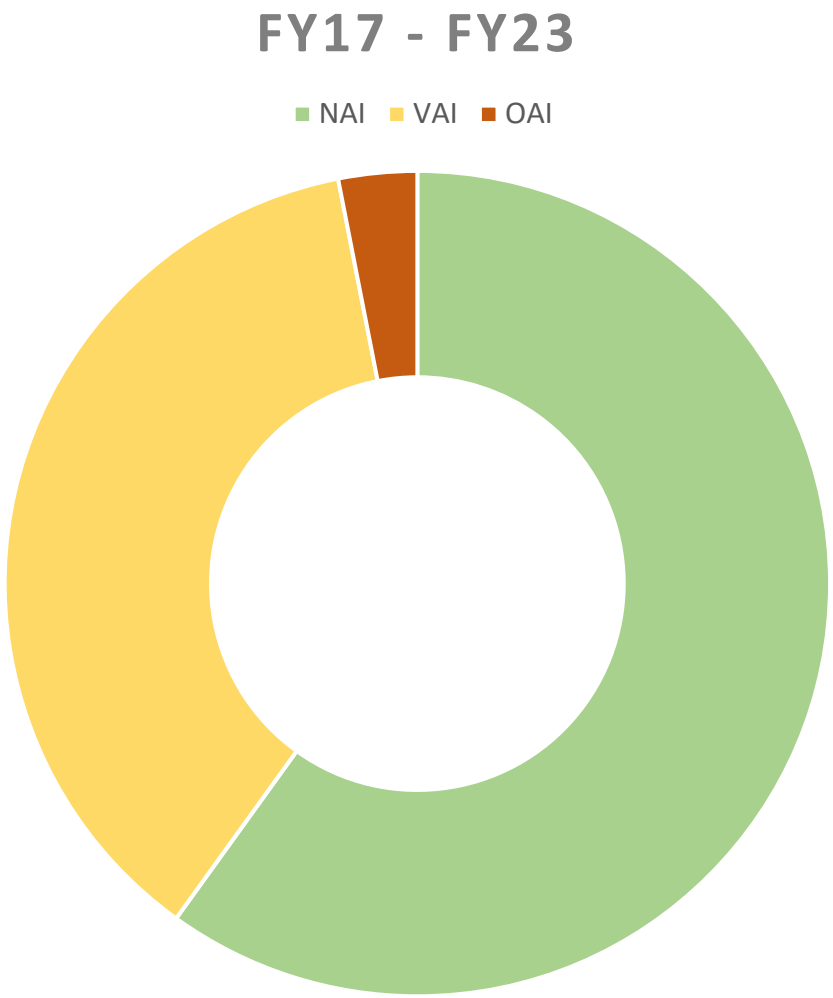


on pace for FY19 numbers

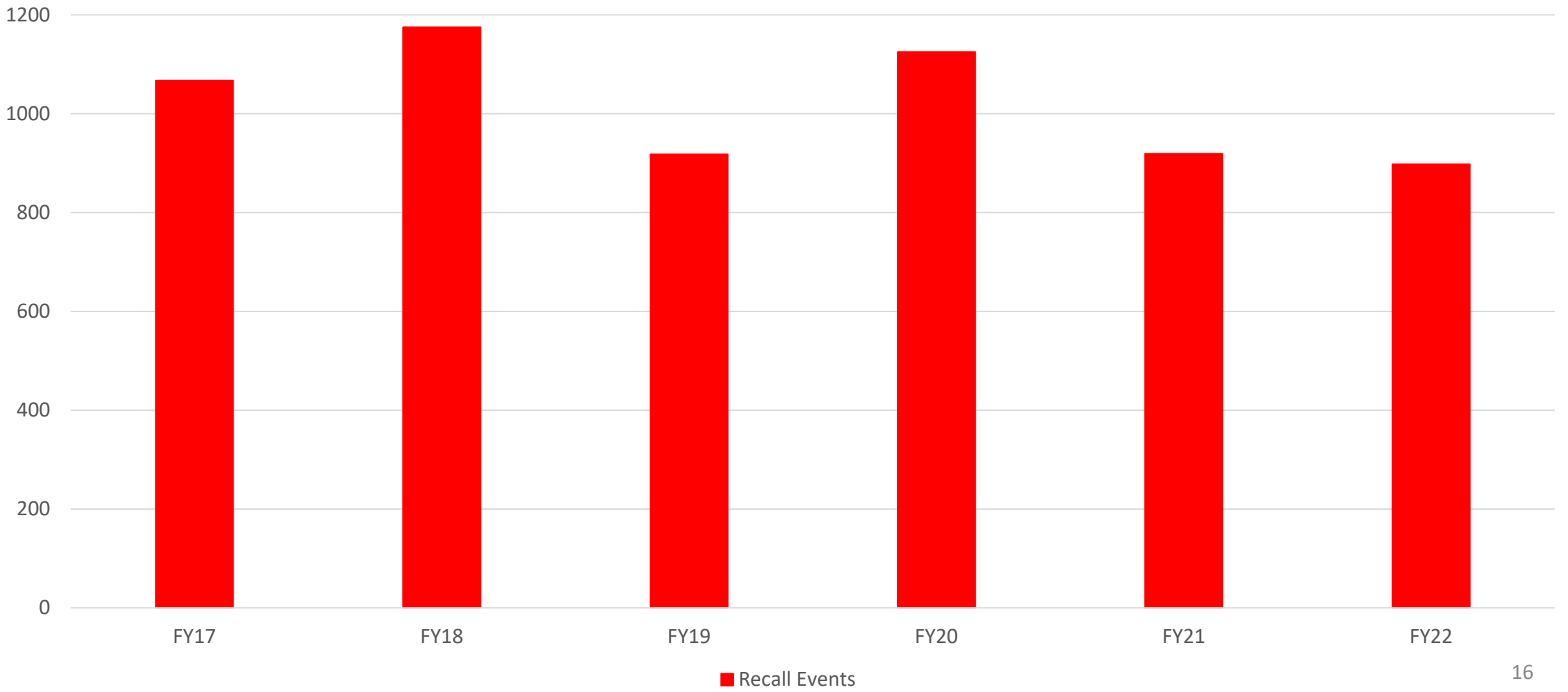


Inspection Classifications



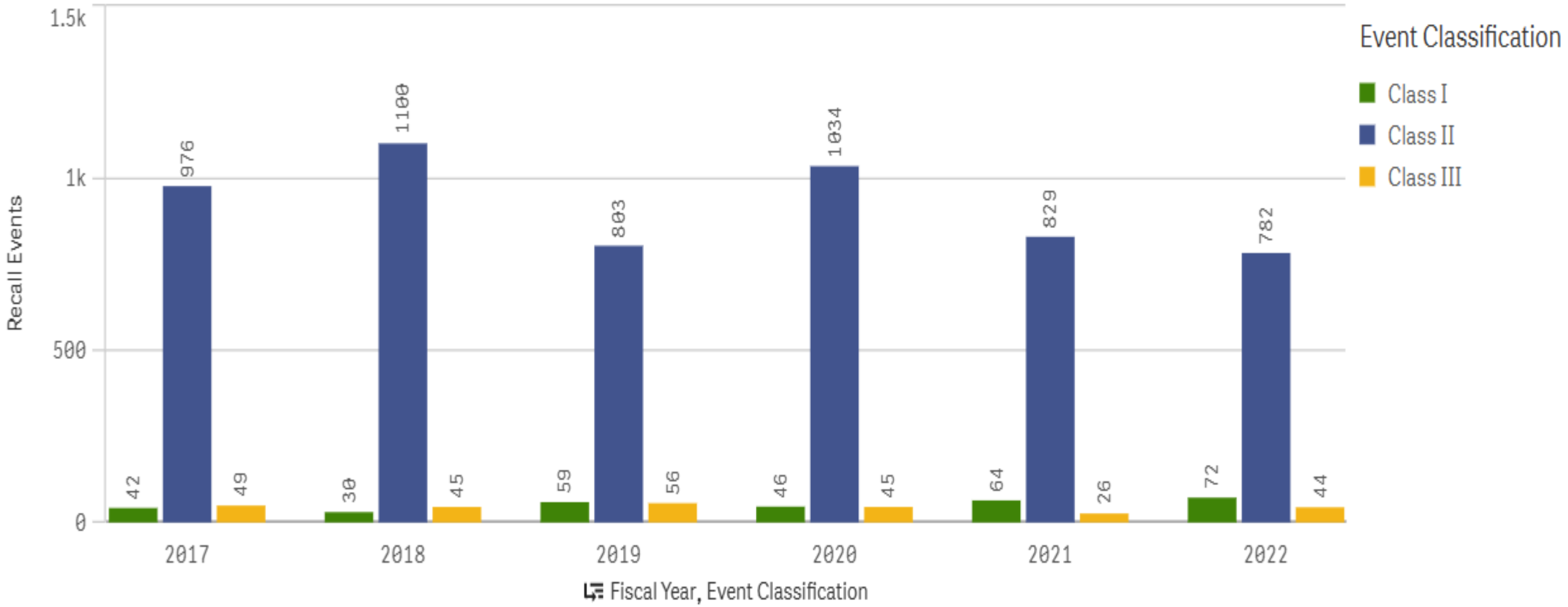


Recall Events by FY



Recall Events Classification

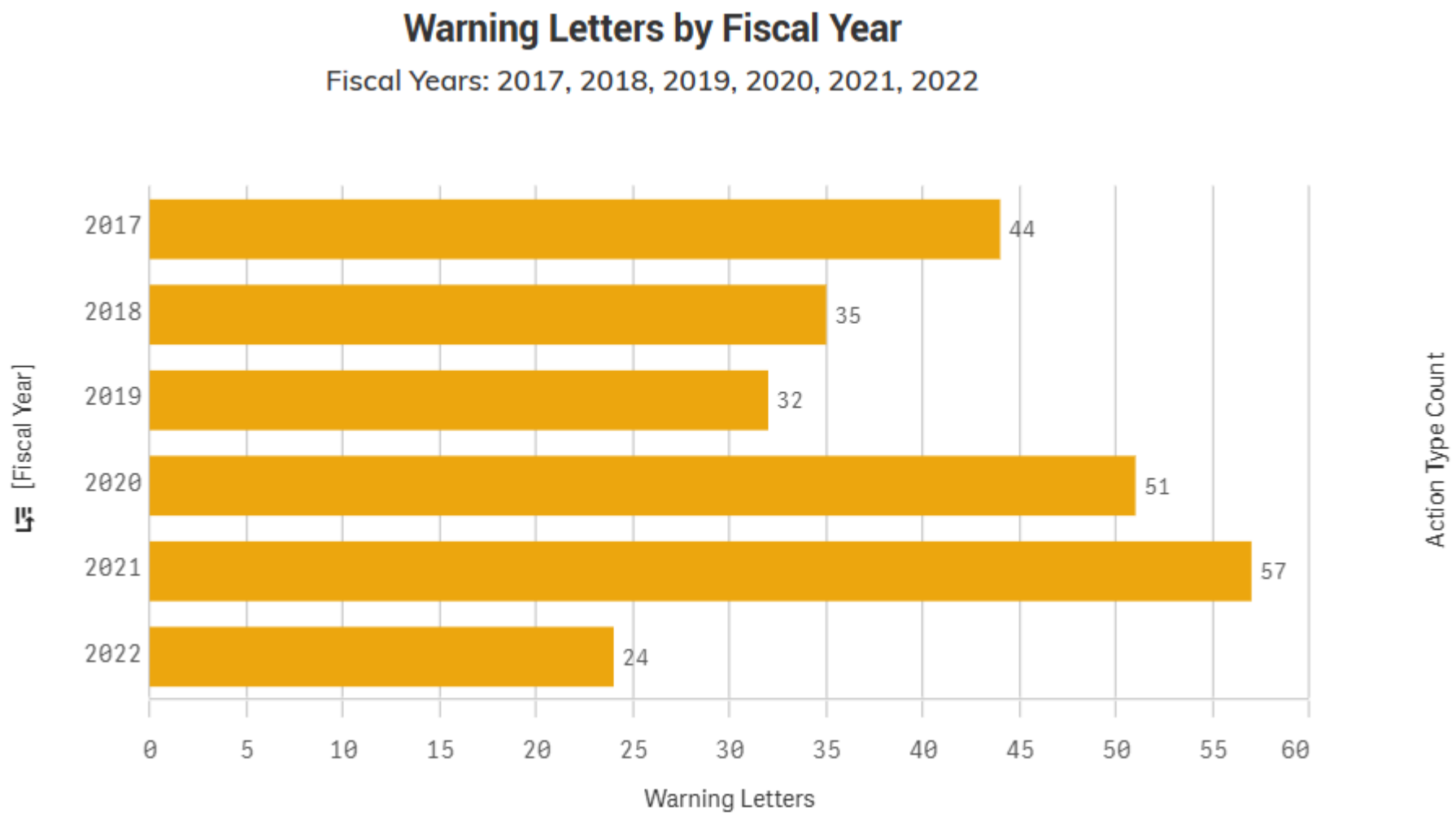
FDA U.S. FOOD & DRUG ADMINISTRATION
DATA DASHBOARD
Data Dashboard Home Compliance Dashboards

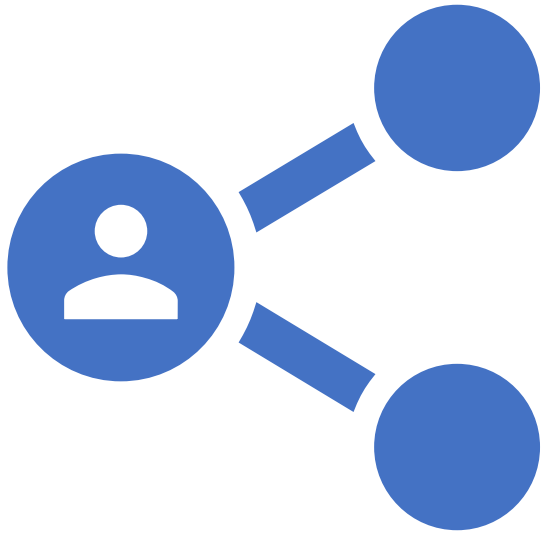


Warning Letters by FY

FDA U.S. FOOD & DRUG ADMINISTRATION
DATA DASHBOARD

Data Dashboard Home Compliance Dashboards





COLLABORATION

OMDRHO, CDRH, Industry & Academia

Stakeholder Outreach

- Education
- OMDRHO Conference
- Industry Talks & MedCon Tradition
  - **Upcoming ORA Talks:**
    - **Day 1**
      - Are You Assuring All Your Suppliers Are Meeting Purchasing Controls Requirements
      - The Do's and Don'ts of 483 and Warning Letter Responses
    - **Day 2**
      - Update on Proposed Rule Aligning QSR With 13485 (QMSR)
      - Demonstration on FDA Databases and Publicly Available Tools
    - **Day 3**
      - Investigator Insights
      - Understand the Recalls Process from Initiation to Termination!

OMDRHO webpage on fda.gov

www.fda.gov/ORADevices

FDA U.S. FOOD & DRUG ADMINISTRATION

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Office of Medical Device and Radiological Health Operations (OMDRHO)

A Day in the Life - Medical Device Program

Frequently Asked Questions About FDA Inspections of Combination Products

OMDRHO 2022 Annual Virtual Conference - 07/13/2022

Working Together - Keeping Informed: FDA Medical Device Virtual Conference 2021 -

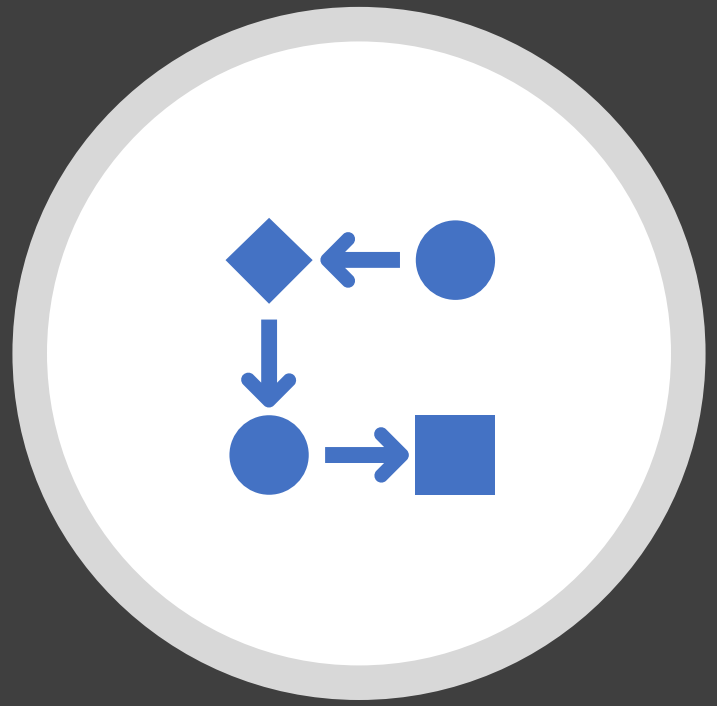
What We Do

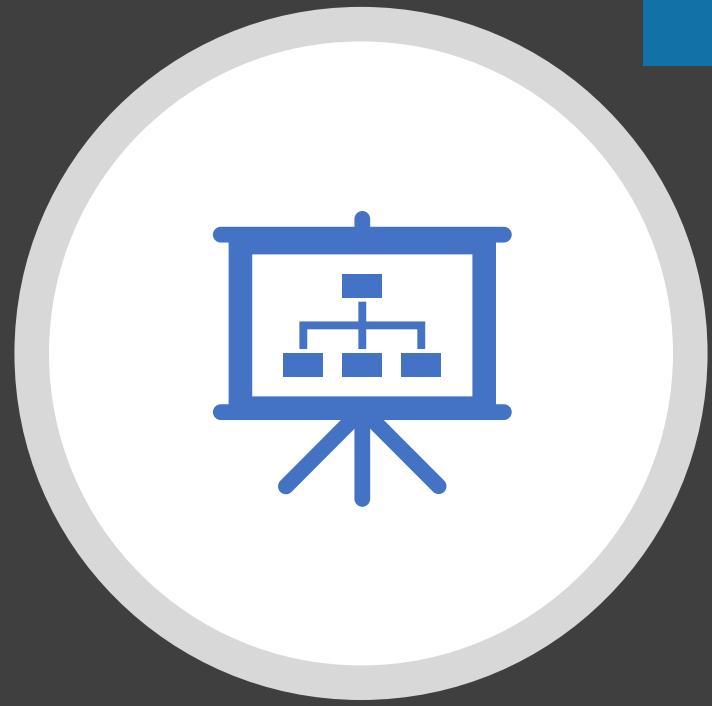
- Inspections
- Remote Regulatory Assessments (RRA)
- Recalls
- Compliance
- Medical Device Databases
- CDRH Related Links
- Additional Information

Content current as of:
02/22/2022

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

Strategic work with CDRH





Medical Device and Radiological Health Quality and Compliance Program Vision Statement

To collaboratively advance and continuously improve the quality, safety, and effectiveness of medical devices and radiological health products to meet patient needs.

One Medical Device Program Themes

1. Advance stakeholder access to modern technology, innovative products, and science based information
2. Ensure patient and consumer health by promptly, efficiently, and strategically addressing product safety issues
3. Foster product excellence and manufacturing innovation to improve product safety, effectiveness, and availability
4. Cultivate a culture of workforce excellence, innovation, and continuous improvement to advance regulatory science and improve public health

CDRH & ORA Program/Initiatives (some)

FDA's Remote Oversight Tools | FDA

Patient Engagement Advisory Committee | FDA

How to Study and Market Your Device | FDA

Total Product Life Cycle Advisory Program (TAP) | FDA

Collaborative Communities: Addressing Health Care Challenges Together | FDA

CDRH Strategic Priorities and Updates | FDA

Conducting Remote Regulatory Assessments Questions and Answers | FDA

Case for Quality | FDA

Updated Compliance Program 7382.845

Questions?

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U.S. FOOD & DRUG
ADMINISTRATION

Thank You!