Current Compliance Trends in OMDRHO

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Objectives

Overview of OMDRHO Compliance Branch

Data Trends and Charts

FDA 483 Responses

Warning Letter's, Regulatory Meetings, Untitled Letters

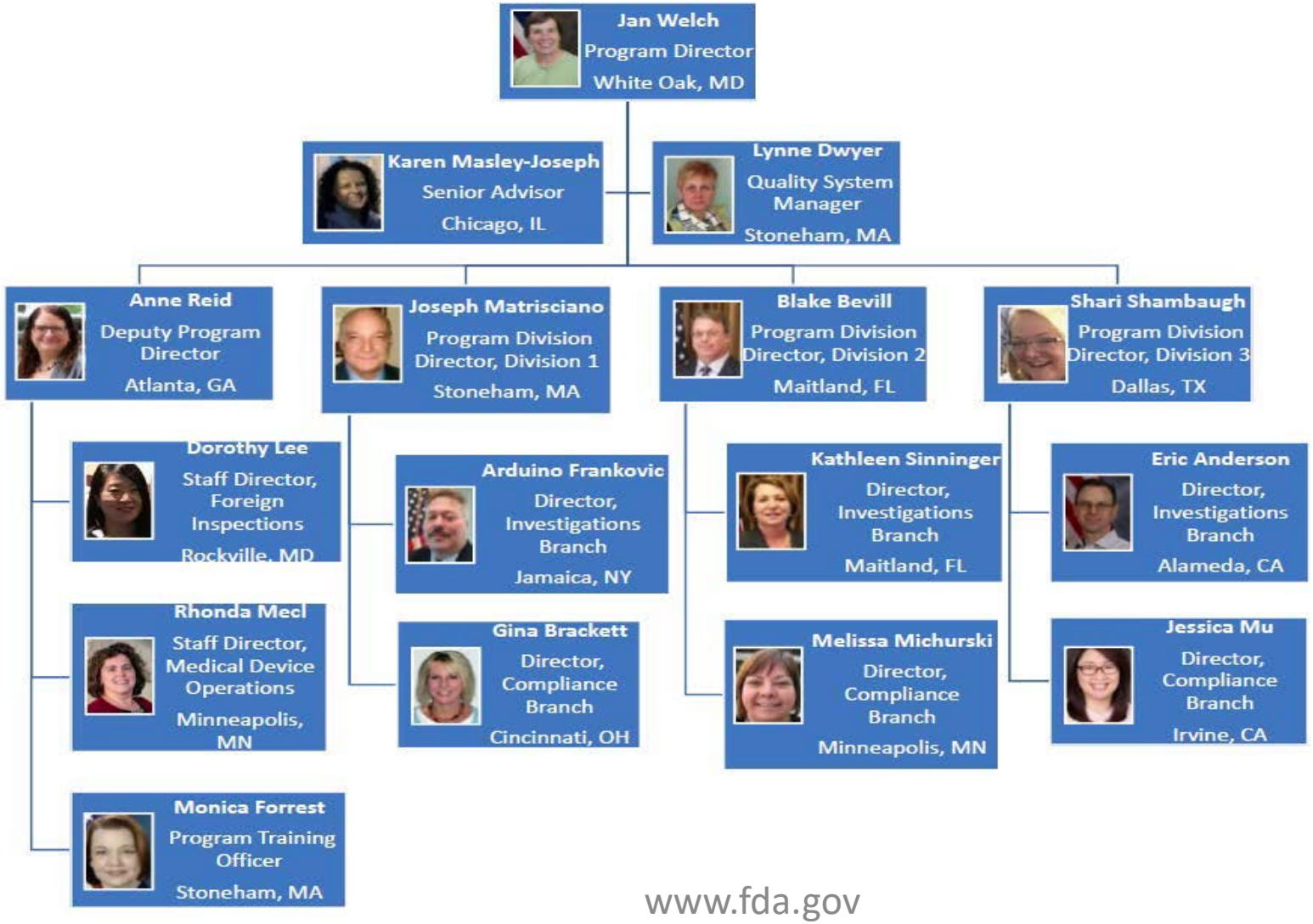
Questions

OMDRHO's Mission Statement

"*Protect and enhance public health through promotion of positive health outcomes while minimizing risk associated with medical devices and radiological health products".*

OMDRHO Organization

Office of Medical Devices and Radiological Health Operations Senior Leadership Team



Compliance Branch Overview

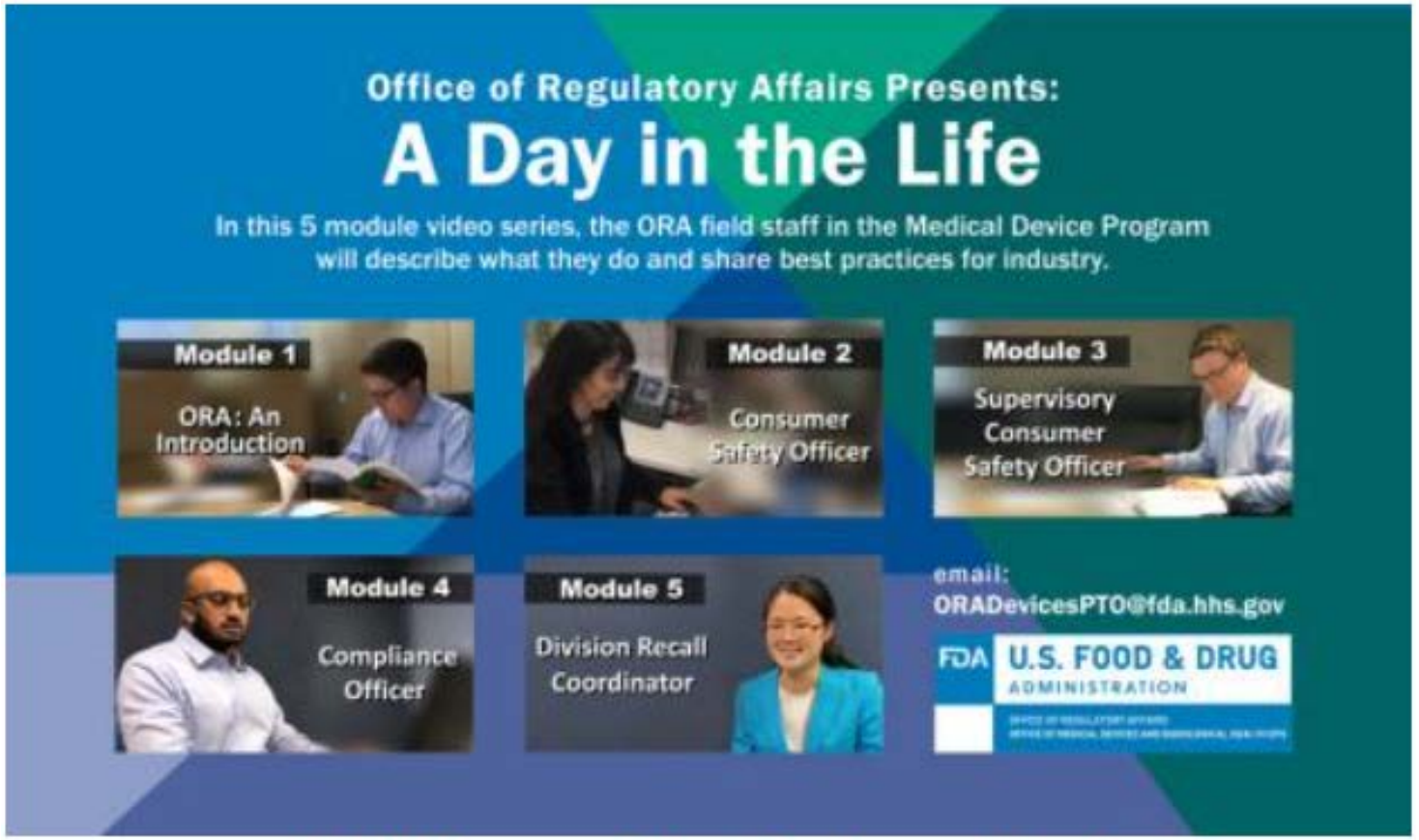
Division	Director of Compliance	Compliance Officers	Recall Coordinators
1	Gina Brackett	Karen Archdeacon Ricard Cherry Amy Cramer Robert Maffei Sargum Morgan Sean Moynihan	Cynthia Aycock Andrew Lang Melinda Ruiz
2	Melissa Michurski	Wendy Blame Amy Devine Demetria Lueneburg Andrea Norwood Rafael Padilla Salvatore Randazzo David Vanhouten	Meredith Andress Marie Fink Lisa Warner
3	Jessica Mu	Ray Brullo Jamie Bumpas Charles Chacko Lauren Priest Jeff Wooley	Mark Chan Paul Frazier Theresa Kirkham

Compliance Branch Overview

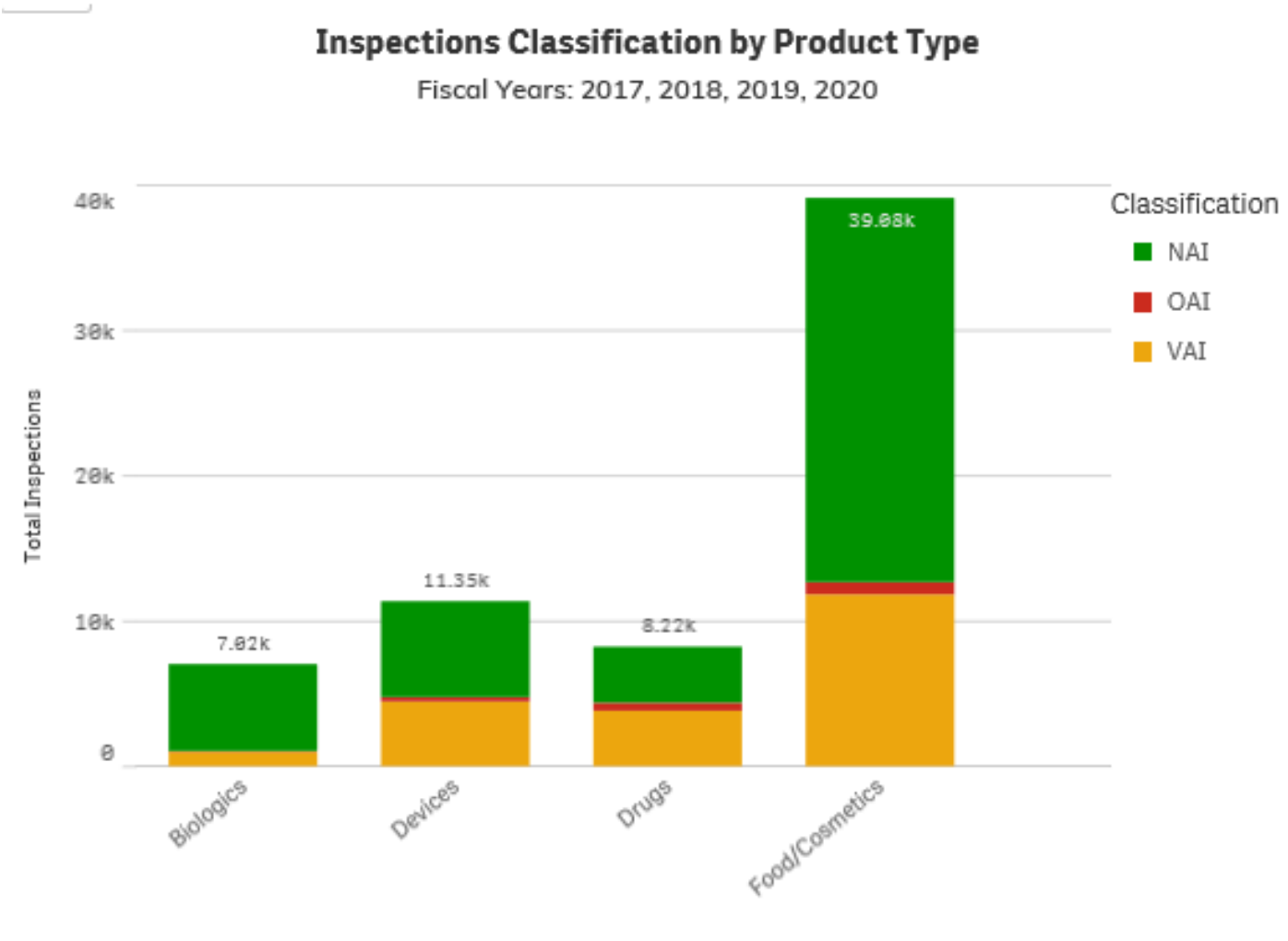
- What do OMDRHO Compliance Officers do?
  - We respond to firm's 483 Responses
  - We prepare and execute advisory, administrative & judicial actions when necessary
  - We perform outreach activities

Outreach Activities

[A Day in the Life Video Series]



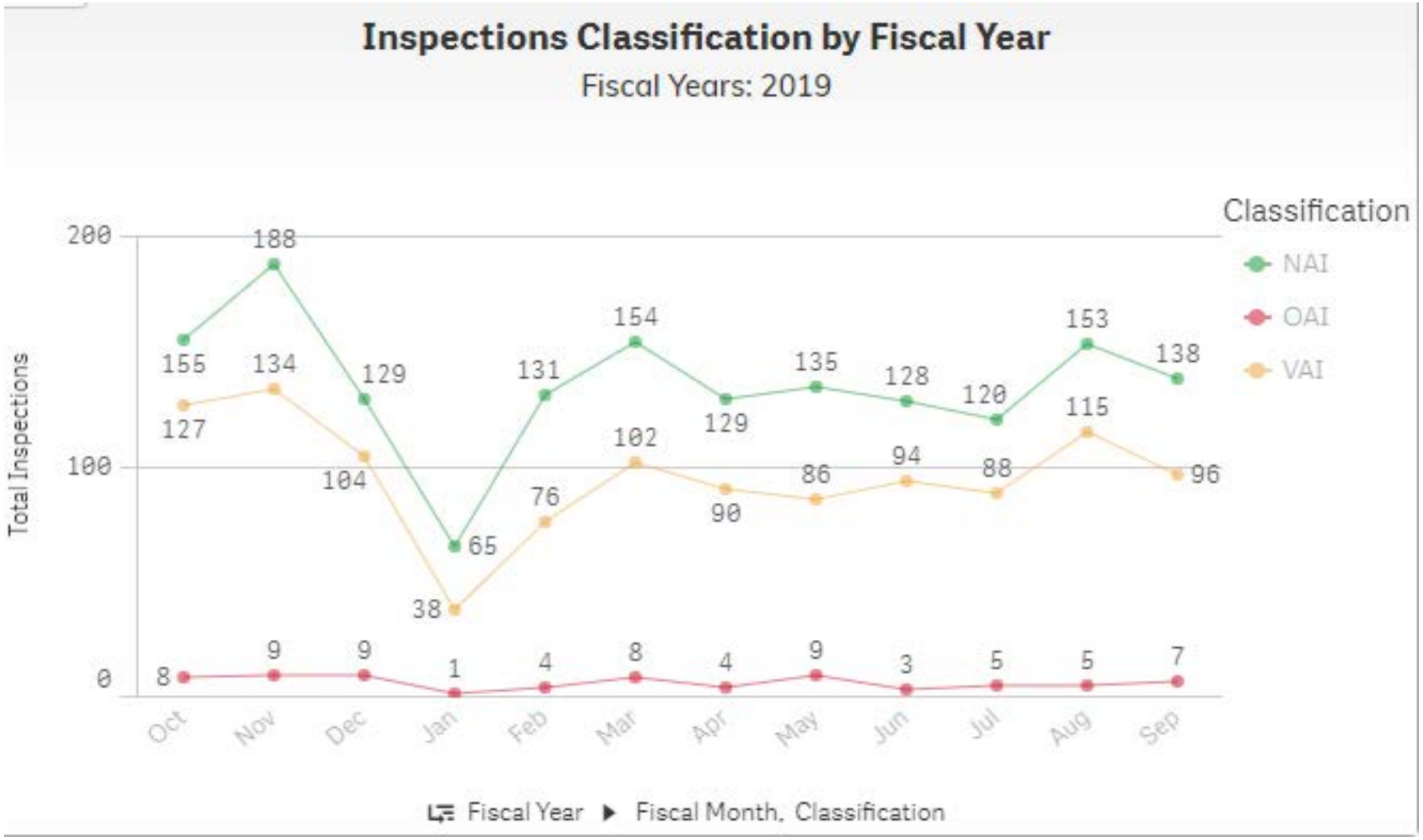
FDA Inspections



Inspection Outcomes

- NAI – No Action Indicated
- VAI – Voluntary Action Indicated
- OAI – Official Action Indicated

FDA Device Inspections



FY2019 QS Medical Device Inspections

Total Domestic Inspections			Total Foreign Inspection		
2847			727		
Domestic Inspection Outcomes		**%**	**Foreign Inspection Outcomes**		**%**
NAI	1625	57%	NAI	207	43%
VAI	1150	40%	VAI	245	52%
OAI	72	3%	OAI	22	5%

Top 5 Device QSR FDA 483 Observations (FY2019)

#	CFR Reference	Description
1	820.100(a)	Corrective and Preventive Action
2	820.198(a)	Complaints
3	820.50	Purchasing Controls
4	820.90(a)	Nonconforming Product
5	820.75(a)	Process Validation

FDA 483 Responses

- Request Response within 15 Business Days
- Electronic Response preferred
- Sent to Program Compliance Branch Director
- OMDRHO will acknowledge responses

FDA 483 Responses

Division	Email
Division 1	ORA DEVICES1 Firm Response <oradevices1firmresponse@fda.hhs.gov>
Division 2	ORA DEVICES2 Firm Response <oradevices2firmresponse@fda.hhs.gov>
Division 3	ORA DEVICES3 Firm Response <oradevices3firmresponse@fda.hhs.gov>

Is the inspection OAI?

- What is Regulatory Significant?
- Compliance Program 7382.845
  - "…documented evidence of one or more major deficiency with QSR."
  - "…would constitute a major problem if not adequately addressed" noncomformity with the QSR and significant risk of the device".
  - "…existence of products that do not conform with manufacturers specifications."
  - "Noncorrection or inadequate correction of major deficiencies from previous inspection"

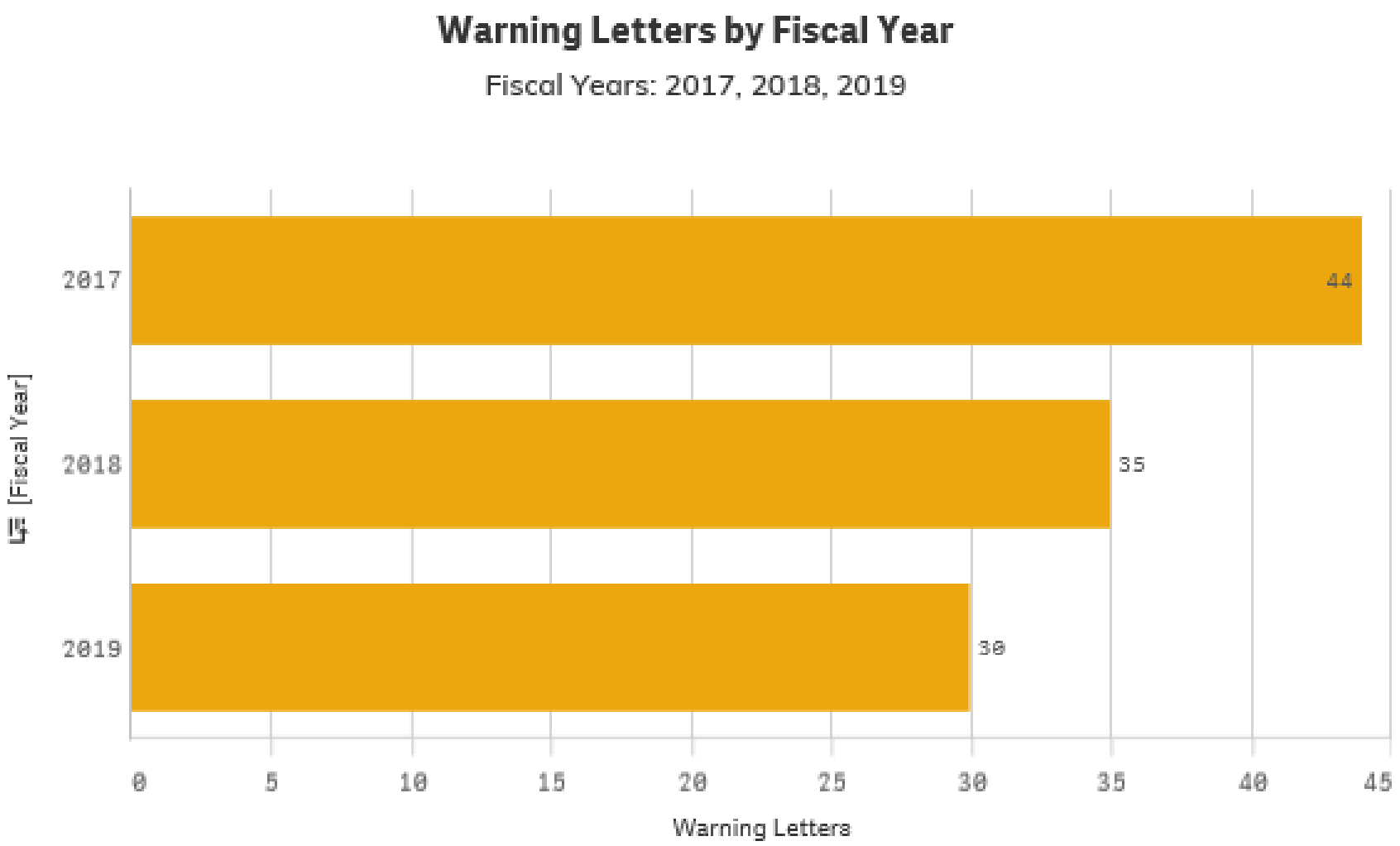
Regulatory Tools

- Warning Letter
- Untitled Letter
- Regulatory Meeting
- Seizure
- Injunction
- Civil Money Penalty
- Recalls, 518(e)

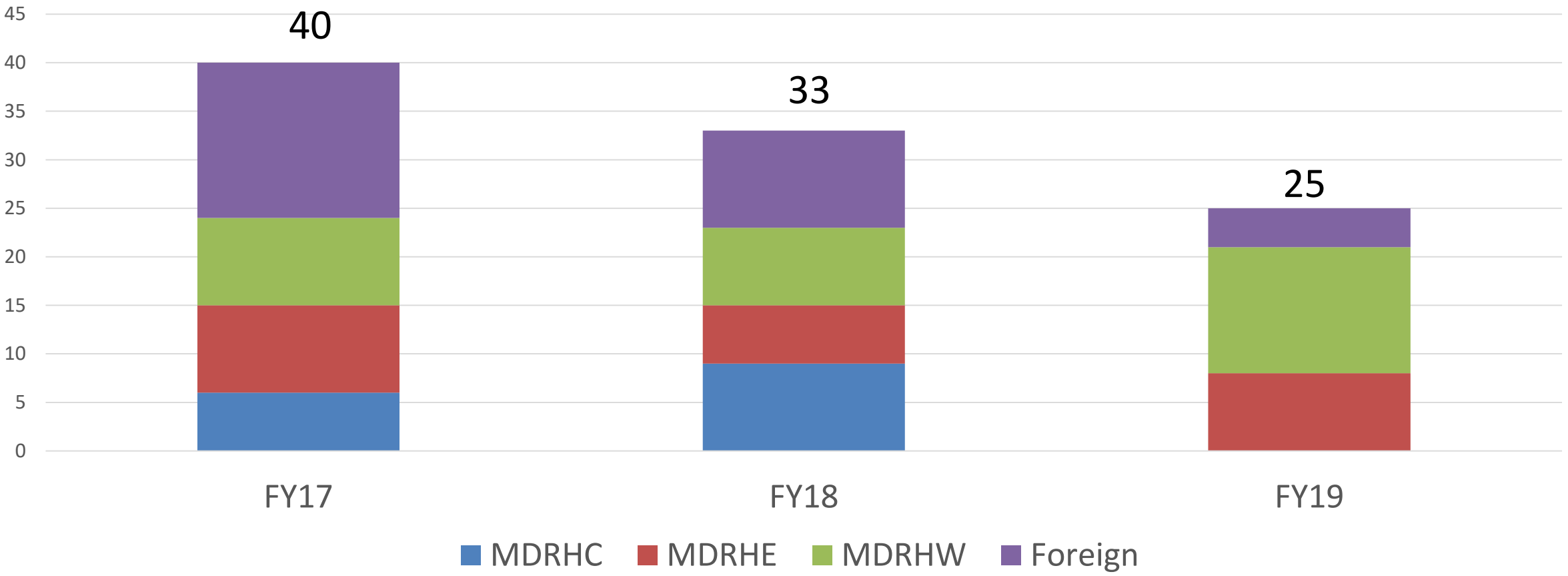
Warning Letters

- Warning Letters are the principal means by which the agency provides prior notice of violations and of achieving voluntary compliance
- Issued only for violations of regulatory significance – i.e., violations that may lead to enforcement action if not promptly and adequately corrected

Warning Letters



Warning Letters



OMDRHO Warning Letters – FY19

Reference	
QSR Violations (104 total)	17
510(k) / PMA Violations	7
Medical Device Report (MDR) Violations	6
Correction and Removal (C&R) Violations	2
Unique Device Identifier (UDI) Violations	1
Registration and Listing	4

Top 5 Device QSR Observations in OMDRHO Warning Letters – FY19

#	CFR Reference	Description
1	820.75	Process Validation
2	820.30	Design Controls
3	820.100	Corrective and Preventive Action
4	820.50	Purchasing Controls
5	820.80	Acceptance Activities

Warning Letter Follow-up

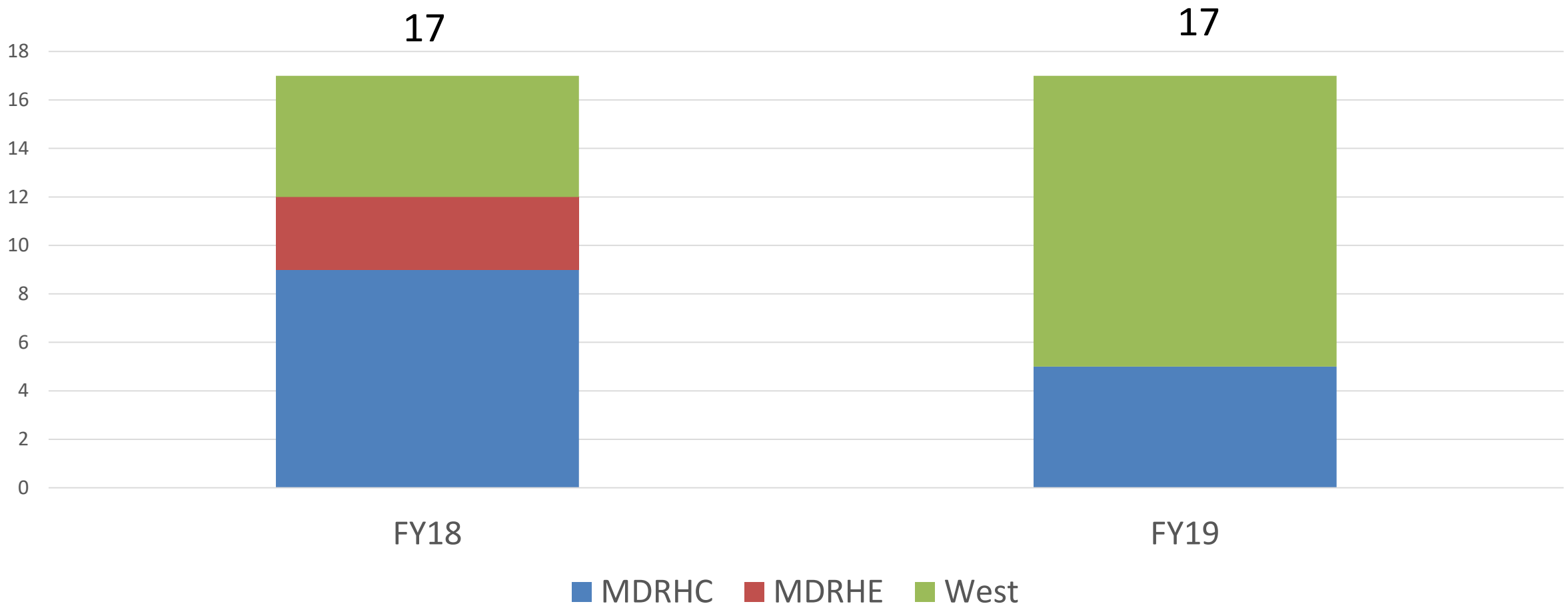
- If f/u EIR finds firm has made corrections and there are no further problems found, then the WL is closed.

- If f/u EIR documents continuing problems, we need to consider additional options

Untitled Letters

- An Untitled Letter cites violations that do not meet the threshold for significance of regulatory significance for a Warning Letter.
- Untitled Letters are an effective enforcement tool to obtain prompt voluntary compliance, and have been used successfully in a variety of different situations.

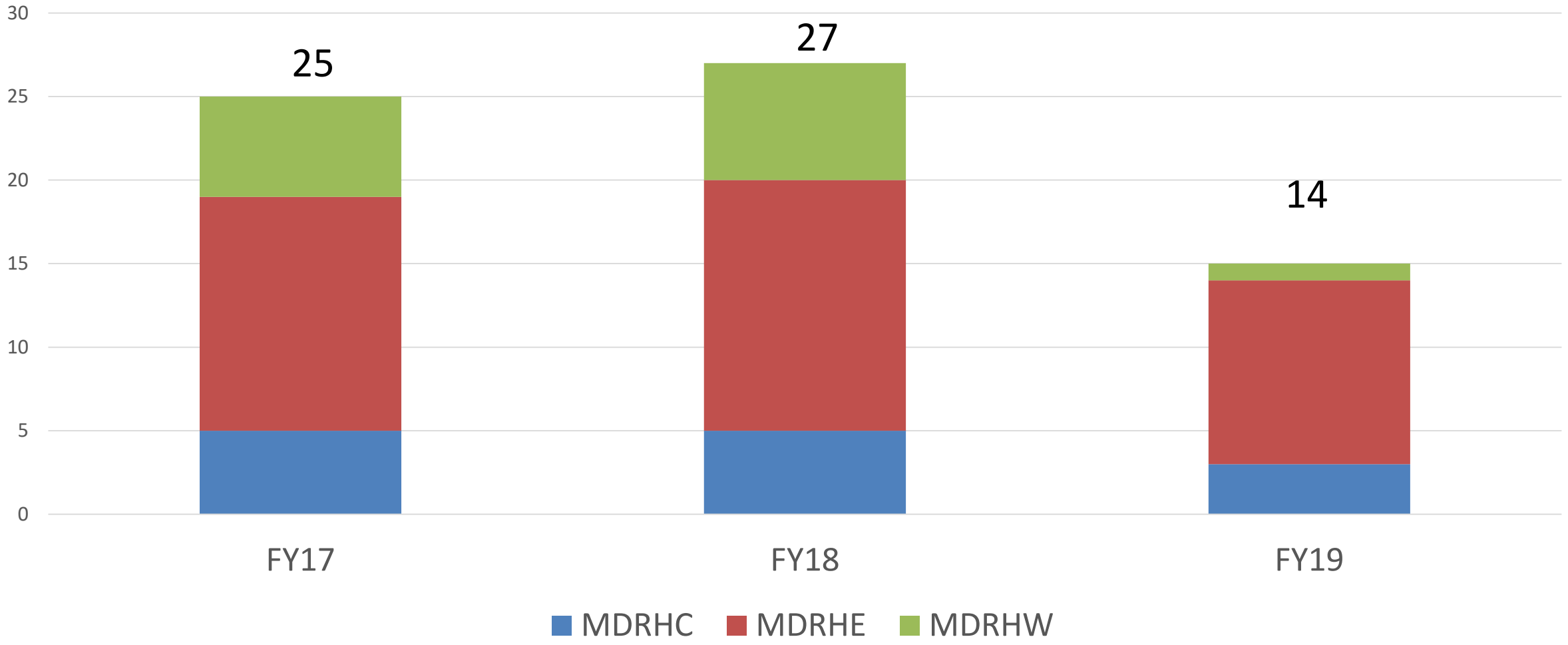
Untitled Letters



Regulatory Meeting

- A Regulatory Meeting is a meeting requested by FDA management at its discretion, to inform responsible individuals or firms about how one or more products, practices, processes, or other activities are considered to be in violation of the law.
- Regulatory Meetings can be an effective enforcement tool to obtain prompt voluntary compliance, and have been used successfully in a variety of different situations.

Regulatory Meetings



Tips for Responding to OMDRHO

- Address each observation / deficiency
- Provide a detailed plan of correction
- Provide evidence of corrections or
- Provide a realistic timeline for corrections if they can not be completed immediately
- Address all discussion items, including premarket issues, that were discussed during an inspection

Questions

Resources

- **Device Advice: Comprehensive Regulatory Assistance**
- https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance

- **OMDRHO Video Series**
- https://www.fda.gov/about-fda/ora-program-areas/medical-device-radiological-health

- **Device Transparency**
- https://www.fda.gov/about-fda/transparency

- **Medical Device Databases**
- https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

Contact Info:

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OPTIONAL SLIDES

Office of Medical Devices and Radiological Health Operations

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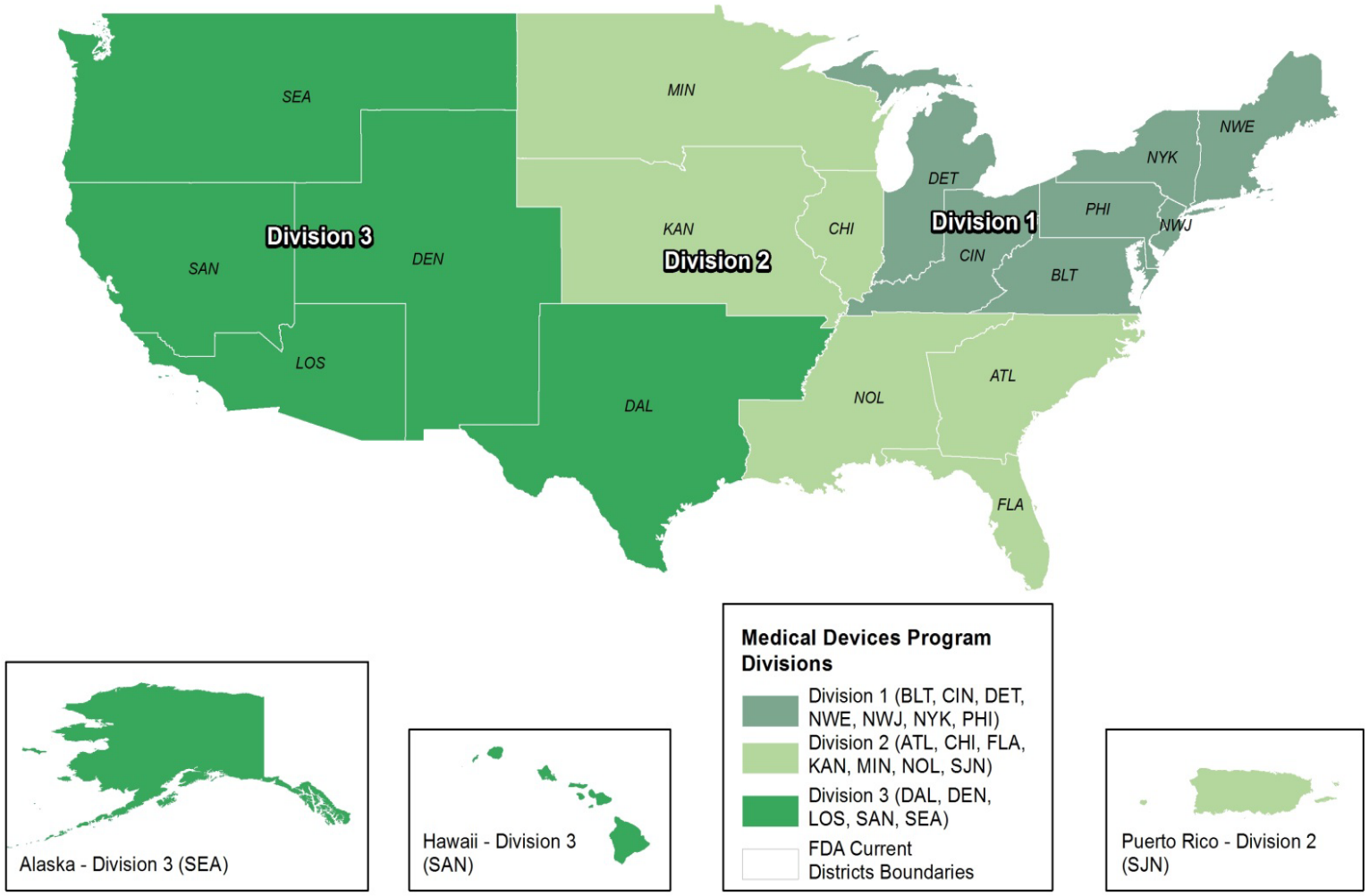

Office of Medical Devices and Radiological Health Operations

Jan Welch
Director
Office of Medical Devices and Radiological Health Operations

- Division of Medical Devices and Radiological Health Operations I
- Division of Medical Devices and Radiological Health Operations II
- Division of Medical Devices and Radiological Health Operations III

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