PROGRAM ALIGNMENT – NEARLY 2 YEARS IN: STRATEGIES FOR INTERACTION WITH FDA FIELD COMPLIANCE

SABPA 14TH ANNUAL BIOMEDICAL FORUM
27APR2019 – SANTA ANA, CA

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FDA Office of Regulatory Affairs
Office of Medical Devices Radiological Health Operations
Division 3/West Compliance Branch

Agenda

- Office of Regulatory Affairs (ORA) – Program Alignment Update and Resources
- Compliance Activities, Metrics, and Response Tips for Industry
- FDARA and 21ST Century Cures
- CDRH 2018-2020 Strategic Priorities

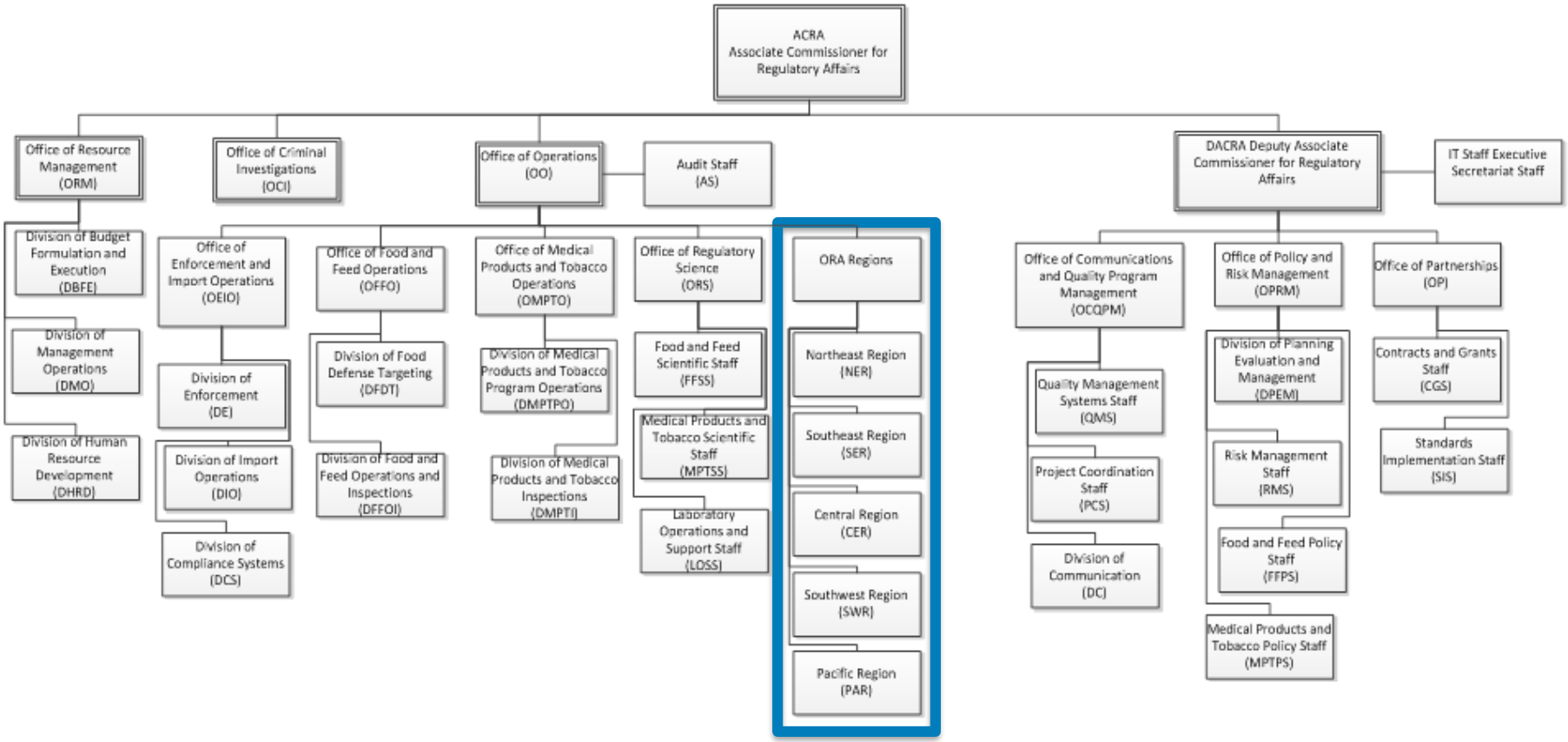
PART 1

> *“…**Modernize** and **strengthen** the **FDA workforce** to improve public health response.”*

2013 FDA Program Alignment Charge

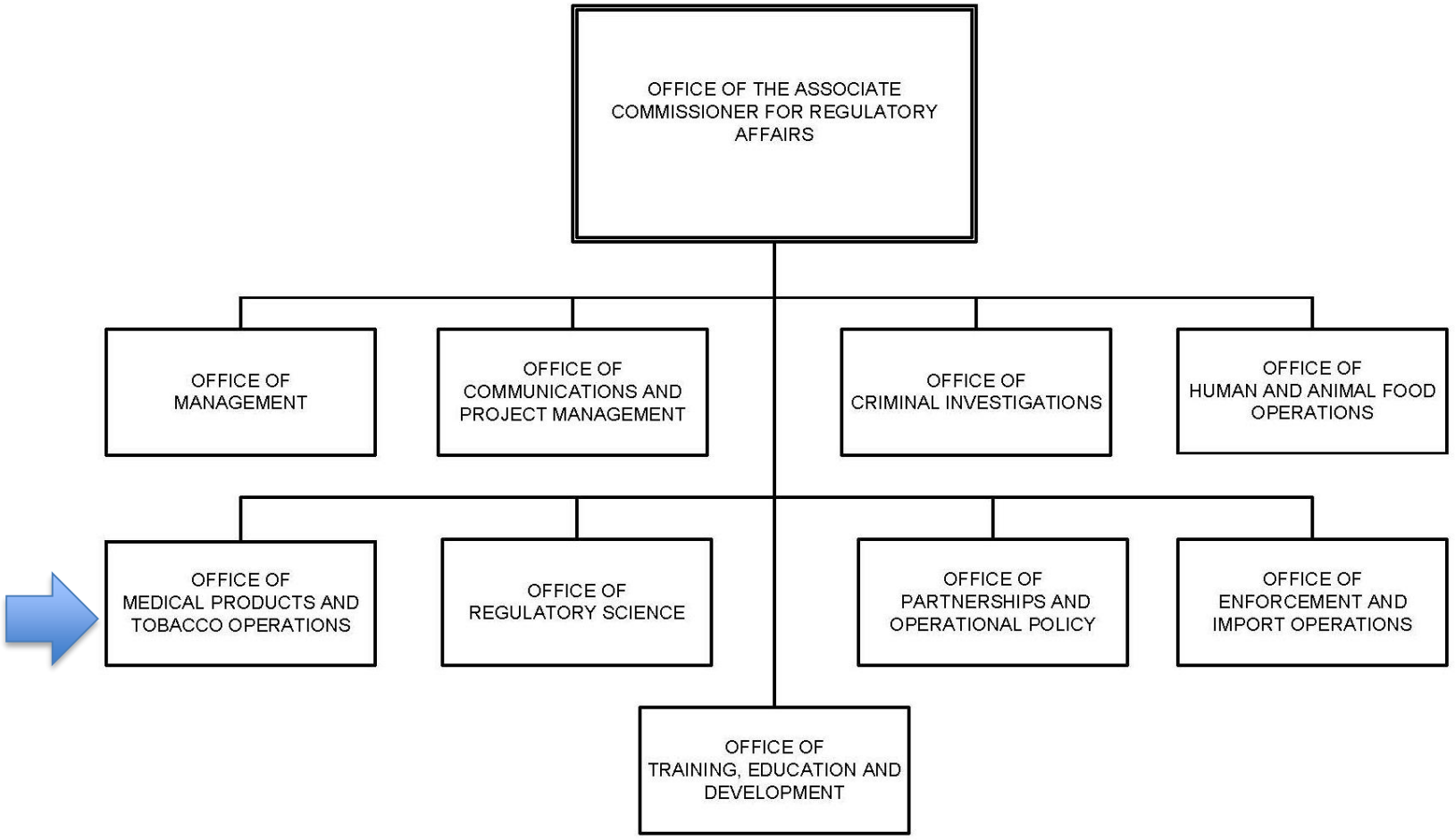
OLD

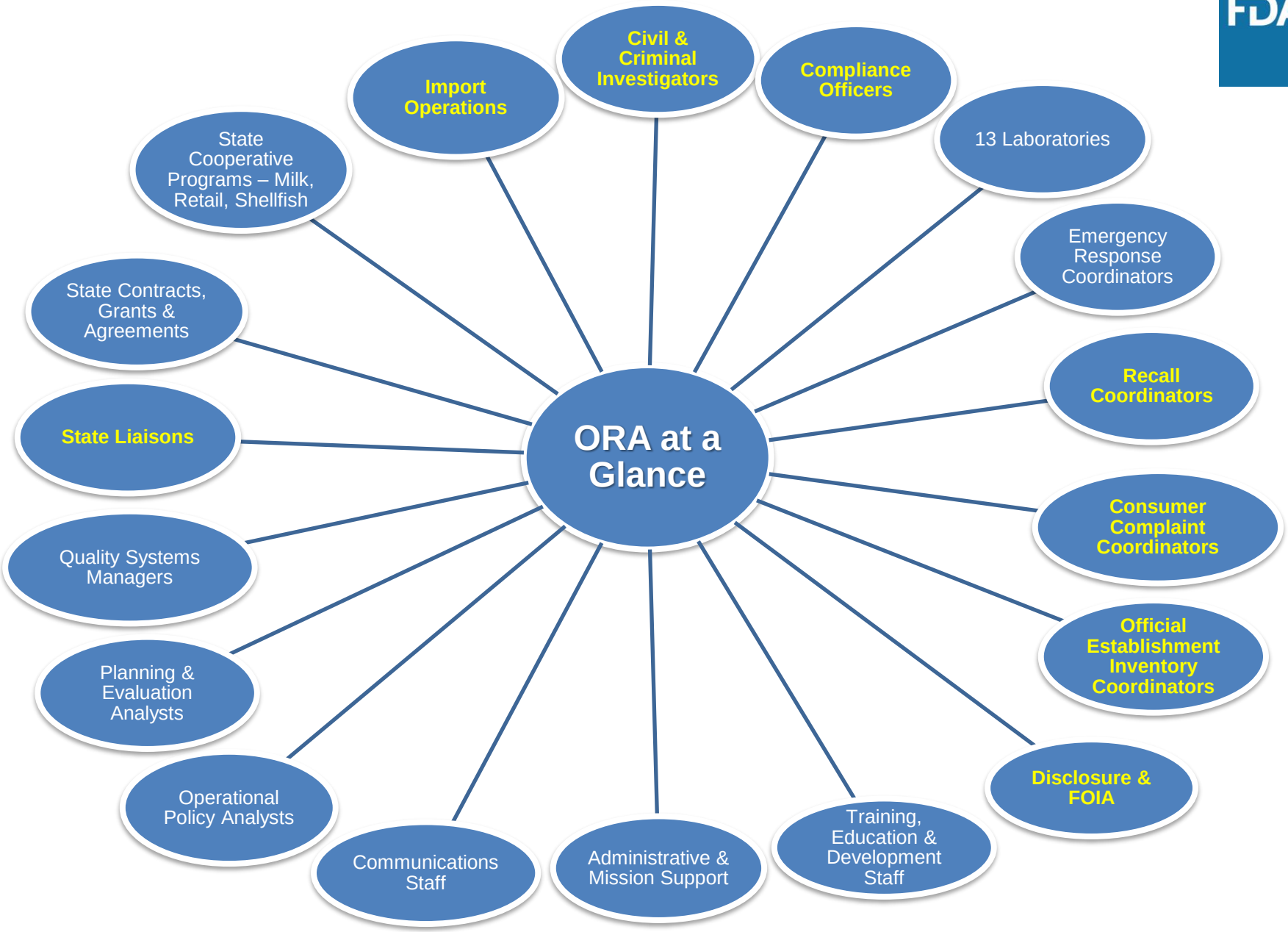
Geographically Aligned Organizational Model



New

Program Aligned Organizational Model




ORA at a Glance
Civil & Criminal Investigators
Compliance Officers
13 Laboratories
Emergency Response Coordinators
Recall Coordinators
Consumer Complaint Coordinators
Official Establishment Inventory Coordinators
Disclosure & FOIA
Training, Education & Development Staff
Administrative & Mission Support
Communications Staff
Operational Policy Analysts
Planning & Evaluation Analysts
Quality Systems Managers
State Liaisons
State Contracts, Grants & Agreements
State Cooperative Programs – Milk, Retail, Shellfish
Import Operations

Program Alignment: Key Changes

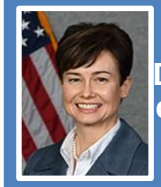
From	To
Geographic management of operations	Program management of operations, management teams based on staff: • Bioresearch Monitoring 2 management teams • Medical Device and Radiological Health 3 management teams • Plus Imports as a program 5 management teams
Degrees of program specialization for investigations, compliance and operational managers	Exclusive specialization in one program for investigations, compliance and operational managers
20 District Directors who manage the geographic district and all programs operations within the district	20 District Directors who manage the geographic district and only one program for operations. Plus eight new program division directors who manage program operations only – total 28 management teams
One import district and a range of import operations embedded within the 16 other districts	Five import divisions (four new import divisions) covering all borders, managing import operations nationally as a program

Office of Medical Products and Tobacco Operations

Ellen Morrison
Assistant Commissioner
Office of Medical Products and Tobacco Operations

Director
Tobacco Staff
[vacant]

Ginette Michaud, MD
Director, Office of Biological Products Operations



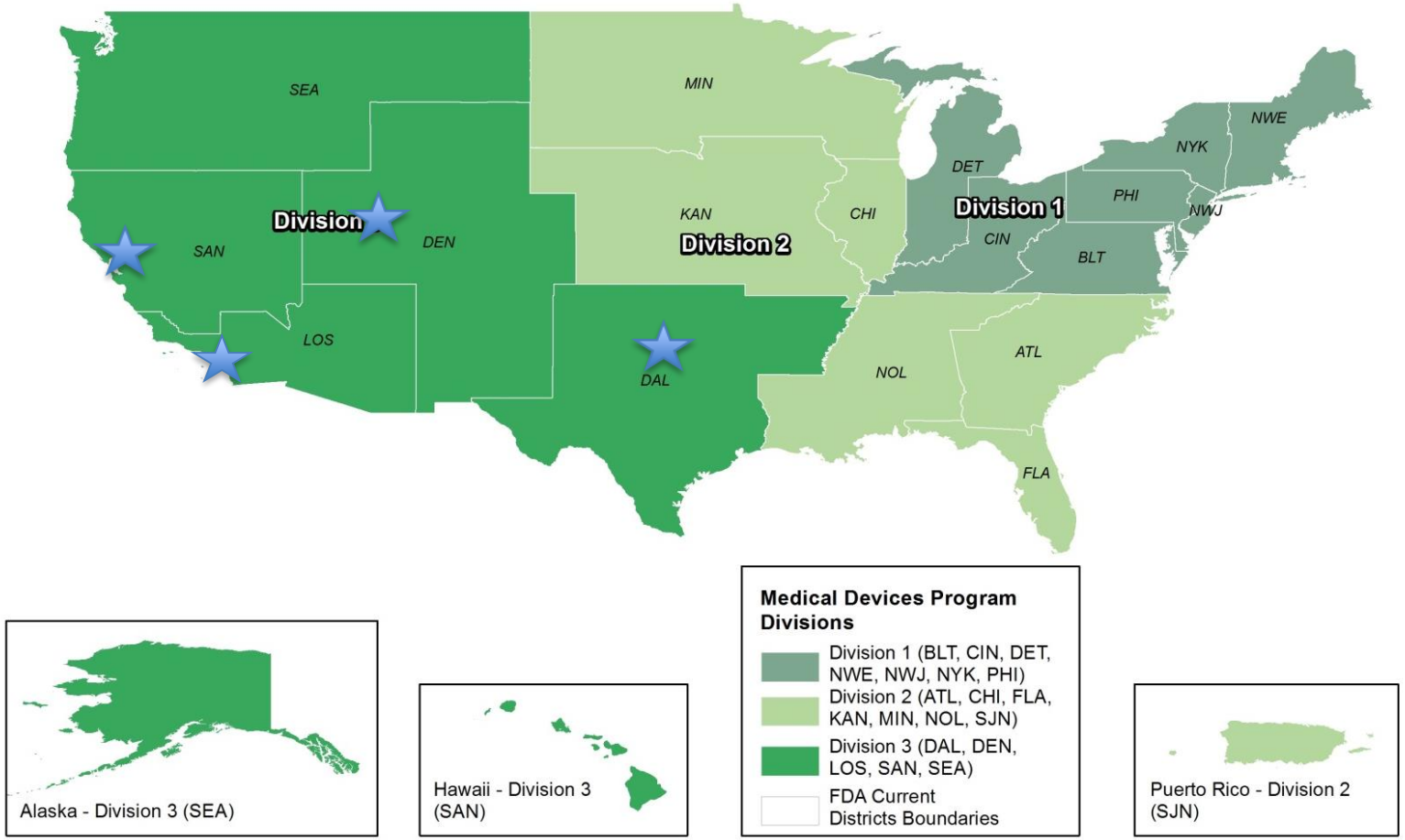
Chrissy Cochran, PhD
Director, Office of Bioresearch Monitoring Operations

Jan Welch
Director, Office of Medical Device and Radiological Health Operations

Alonza Cruse
Director, Office of Pharmaceutical Quality Operations

Office of Medical Device and Radiological Health Operations

Office of Medical Device and Radiological Health Operations



FDA EXTERNAL FACT SHEET

- https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/UCM558298.pdf

About the Office of Medical Device and Radiological Health Operations

A specialized office to help protect and promote the safety and quality of medical devices and radiation-emitting products.

The Office of Medical Device and Radiological Health Operations (OMDRHO), a program within the Office of Medical Products and Tobacco Operations in the Office of Regulatory Affairs (ORA), provides advice and counsel to ORA and FDA leaders regarding medical device and radiological health program operations, including emergency response activities. OMDRHO collaborates with the agency's Center for Devices and Radiological Health (CDRH) on all FDA-regulated medical devices and radiation-emitting products.

OMDRHO coordinates, directs and assists with medical device and radiological health inspectional activities, including conducting inspections of medical devices and radiation-emitting products, as well as providing technical assistance regarding medical devices and radiological health inspectional operations. ORA and CDRH partner to develop annual work plans and strategic priorities for inspections, compliance, analysis, and import operations as part of FDA's implementation of the, Medical Device User Fee and Modernization Act.

https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/default.htm

About the Office of Regulatory Affairs

- ORA Vision, Mission, and Values
- ORA Overview
- ORA Accomplishments
- ORA Program Division Boundary Maps and Fact Sheets
- Office of Regulatory Affairs Executive Advisory Council (EAC) Listing
- Program Alignment and ORA
- ORA Ombudsman
- Contact ORA
- ORA FOIA Electronic Reading Room
- I Am ORA

Resources for You

- FDASIA Title VII Drug Supply Chain Provisions
- For Federal, State, and Local Officials
- Inspection References
- Compliance Manuals
- ORA University (ORAU)
- Field Science and Laboratories
- Inspection Classification Database
- Office of Regulatory Affairs History

About the Office of Regulatory Affairs

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The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. In pursuit of its mission, ORA also works with its state, local, tribal, territorial and foreign counterparts.

ORA News

- FDA and CBP bolster collaboration to protect public health and safety
- Statement from FDA Commissioner Scott Gottlieb, M.D. on the agency's 2019 policy and regulatory agenda for continued action to forcefully address the tragic epidemic of opioid abuse
- Statement by FDA Commissioner Scott Gottlieb, M.D., on risk of heavy metals, including nickel and lead, found in some kratom products
- FDA warns consumers to avoid Rhino male enhancement products found at retailers because of undeclared and potentially dangerous drug ingredients
- Statement from FDA Commissioner Scott Gottlieb, M.D., on the

Spotlight

- Enforcement Policy Statement (PDF - 19KB)
- FDA Public Affairs Specialists
- Import Program – Food and Drug Administration (FDA)
- FDA Bioresearch Monitoring Information
- Criminal Investigations

Recalls & Alerts

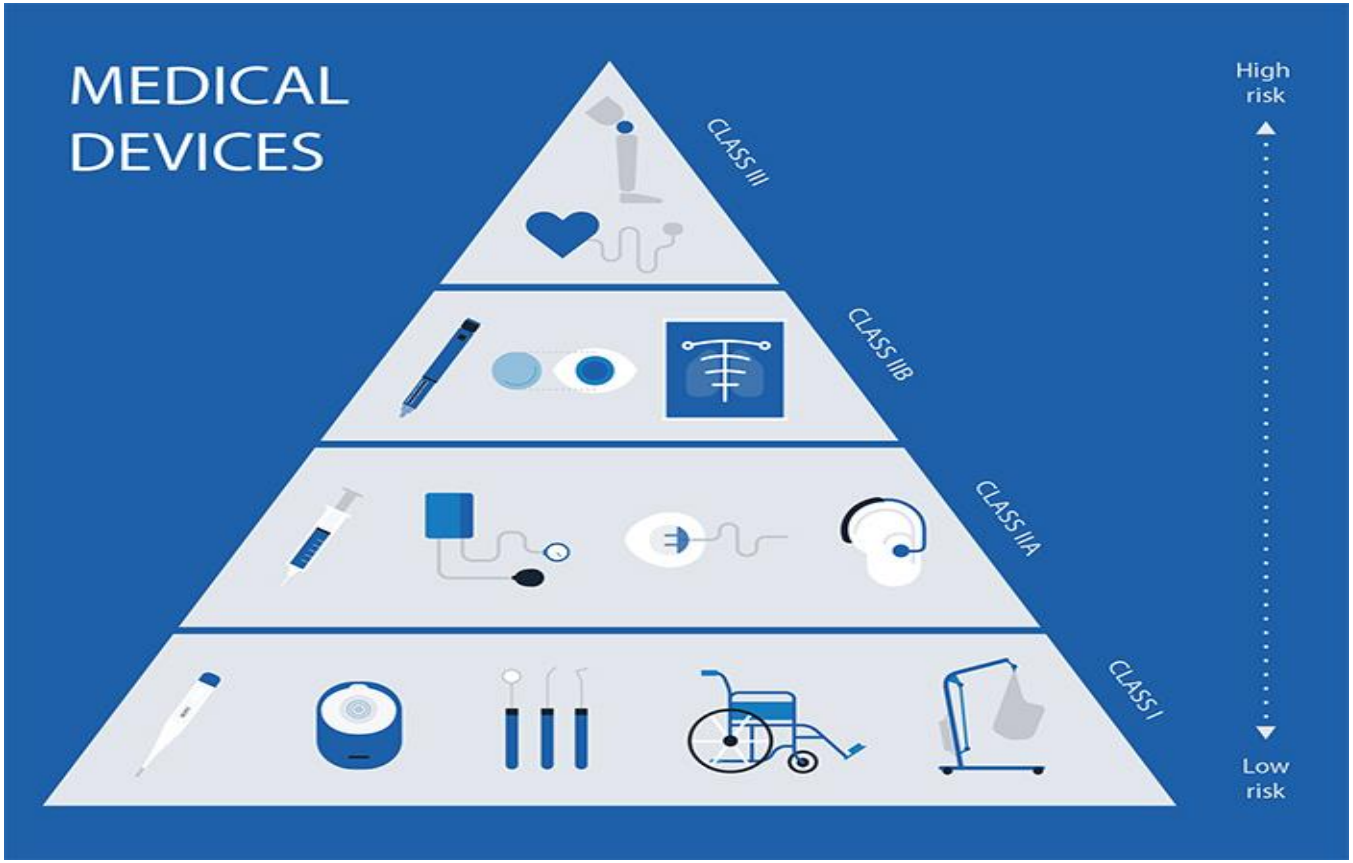
- Recalls, Market Withdrawals, & Safety Alerts
- Import Alerts

Requested Documents

- ORA Directory (PDF - 186KB)
- Regulatory Procedures Manual
- Enforcement Reports
- Inspection Guides
- Investigations Operations Manual

PART 2

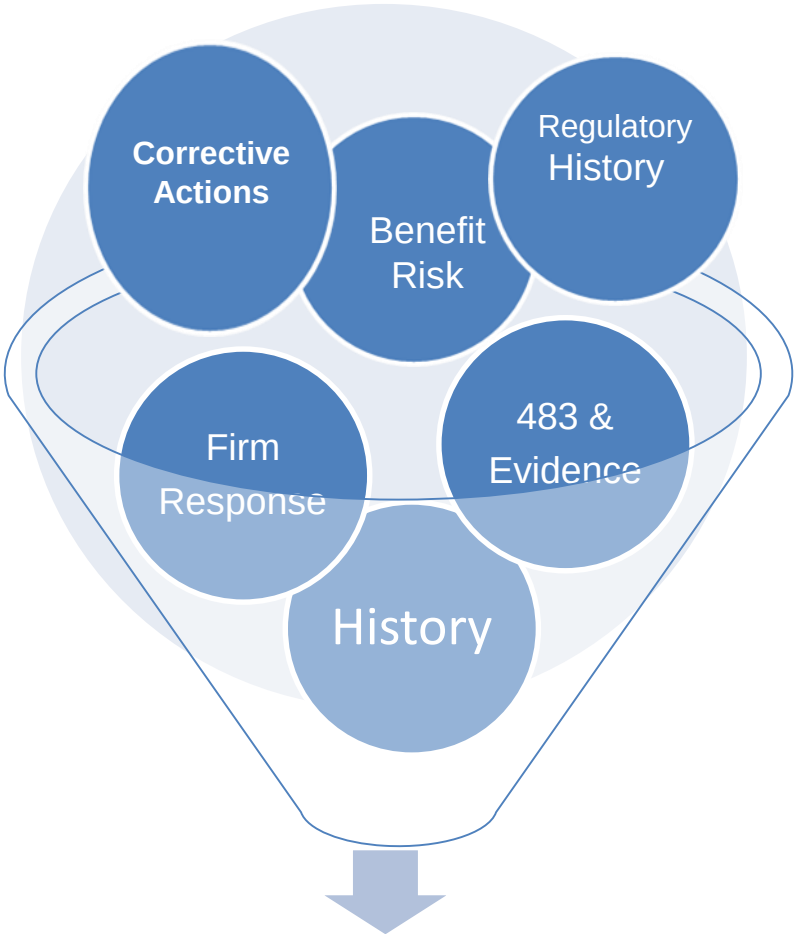
Know Your Product



Know Your Product (Pre & Post Market)

- Does it require premarket notification [510(k)] or application [PMA]?
- How is it classified? Did you list it correctly?
- What are your reporting requirements?
- What are your Quality System requirements?
- What are your label & labeling requirements?
  - Do you have a website, social media? (labeling)

After the inspection…



Compliance Decision/Regulatory Strategy

Optimizing Responses from Firm

- Consider annotating the FDA 483
- Make corrections during inspection
  & provide evidence to investigator
- Address each observation/deficiency specifically and how it relates to the overall Quality System
- Be comprehensive, accurate and show evidence of corrections and corrective actions
- Monitor CAPAs and conduct effectiveness checks

Optimizing Responses from Firm

- Updated/revised SOPs, docs: show before & after versions so that changes are clear to the reader
- Corrective Action Plan: provide timetable, set realistic due dates, and state what will be delivered
- Work closely with your ORA Compliance Officer
- Generally, do not go directly to Investigator, Investigative Supervisor, or CDRH

Correspondence

- Email is preferred for substantive responses oradevices3firmresponse@fda.hhs.gov
- The Division will acknowledge receipt and/or provide a specific reply, as applicable
- Email limit of less than 100 megabytes. Larger files please submit as several files or zip file
- Please label attachments

FY18 Metrics – Domestic Medical Devices

# Inspections	FDA 483s	Injunctions	Seizures	Warning Letters	Total Recalls	Class I Recalls
2626	846 32% of inspections	1	0	34 1.3% of inspections 4% of FDA483s	3286	117

PART 3

"FDARA" (Device User Fee Law)

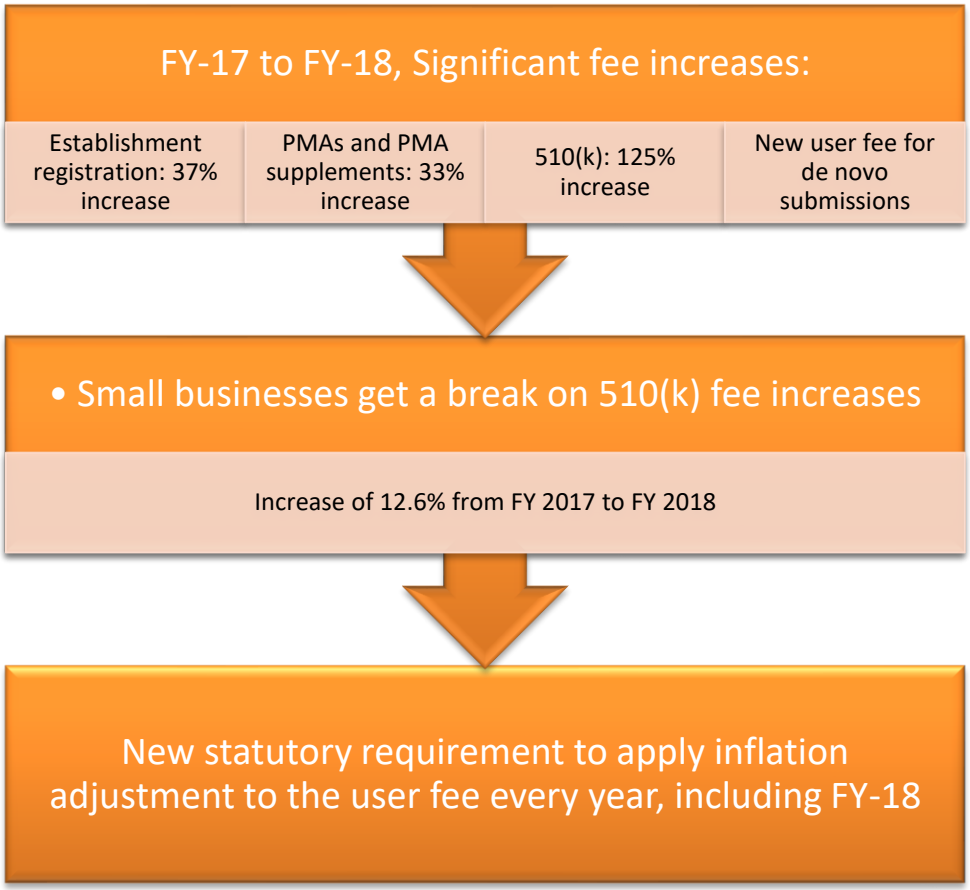
Food and Drug Administration Re-Authorization Act of 2017

Signed into law August 2017

Amends the FD & C Act to revise and extend user fees

Requires FDA to develop public reports, reports to Congress, communications plans, etc.

FDARA User Fee Highlights



FDARA Risk Based Inspection Highlights

- Requires FDA to conduct establishment inspections on a risk based schedule, using the following factors versus statutory biannual inspection for Class II and III device firms:
  - Compliance History
  - History of recalls
  - Inherent risk of the device
  - Inspection frequency and history
    - FDA inspection in the previous 4 years
    - Foreign government inspections
    - Participation in international device audit programs (e.g., MDSAP)

FDARA Uniformity Highlights

- Requires FDA to establish uniform process for routine inspections (not for cause) to include:
  - Pre-announcement of routine inspections
    - Within a “reasonable time”
    - Notification of type and nature of the inspection
  - Estimate of inspection timeframe
  - Opportunity for advance communication regarding working hours and records to be requested
  - Regular communication during the inspection regarding the inspection status
- Draft guidance required by February 18, 2019

FDARA Feedback Highlights

1

New statutory requirement for FDA to provide feedback on a firm's 483 corrective actions, *upon request*

2

Feedback required if:

- Request is "timely"
- Corrective actions relate to:
  - Public health
  - Systemic or major actions, or
  - Emerging safety issue

3

Response within 45 days after receipt of a request

- Feedback is nonbinding

FDARA Inspection Refusals

- Devices are now deemed adulterated if an establishment delays, denies, limits, or refuses an inspection
- FDA Guidance, “Circumstances that constitute delaying, denying, limiting, or refusing a drug inspection (Oct. 2014)
  - Delay
    - Postpones the start of an inspection without reasonable explanation
    - Leaves the investigator without access to requested documents or personnel for unreasonable time
  - Limiting
    - Discontinues manufacturing during inspection or limits direct observation without reasonable explanation
    - Prohibits photography without reasonable explanation
    - Unreasonably redacts requested documents

FDARA CFG Issuance

- FDA must provide written explanation for Certificate to Foreign Government denial unless basis is injunction, seizure, Class I or Class II recall.
- Prohibits CFG denials based solely on 483 observations if the firm "has agreed to a plan of correction"
- Requires there to be a process for review of CFG denials for firms to submit new information
- Requires draft guidance August 18,2018

FDARA: Title IX Section 902

- Annual Report on Inspections
- CY 2018 FDARA Section 902 Annual Report on Facility Inspections Necessary to the Approval of Specified Human Drugs and Medical Devices
- https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/ucm598050.htm

21st Century Cures Act
Law signed December, 2016

- Easier to be a breakthrough device
- Bigger volume allowed for Humanitarian Use
- Recognition of Standards
- Certain Class I and Class II devices
- Classification panels
- Institutional Review Board flexibility
- Diagnostic and CLIA Waiver improvements
- "Least Burdensome"

Global Regulatory Convergence

EU MDR & EU IVDR (certification through Notified Body)

Brexit

MDSAP (US, Japan, Brazil, Canada, Australia)

ISO 13485:2016

QSR

PART 4

CDRH 2018-2020 STRATEGIC PRIORITIES Applicability to ORA?

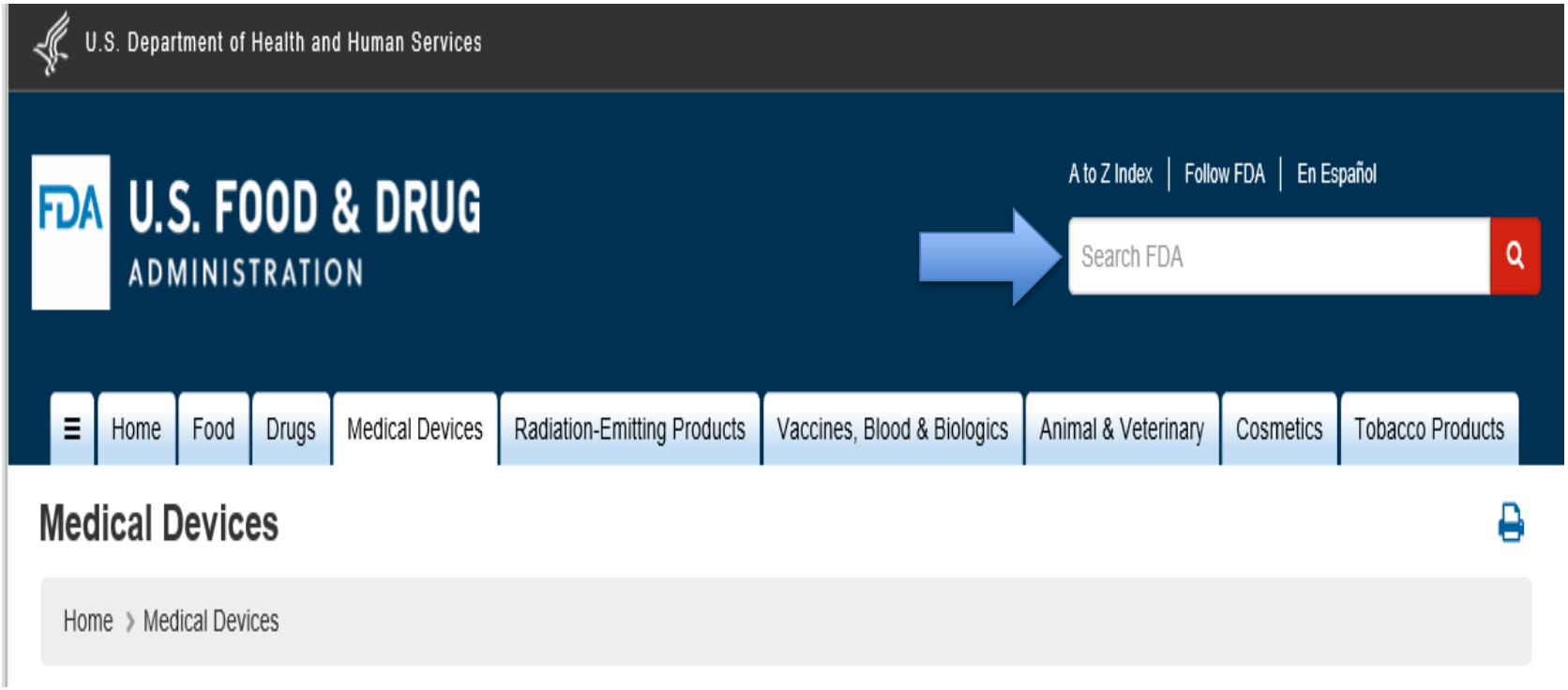
- https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM592693.pdf
- Total Product Life Cycle (TPLC) approach (e.g. Infusion Pump Guidance Dec. 2014)
- Least burdensome approach (Guidance Dec. 2017)

CDRH 2018-2020 STRATEGIC PRIORITIES

- Real world evidence (Guidance Aug. 2017)
- CDRH “super office” [TPLC]
- Flexible regulatory paradigms
- Benefit-Risk framework (Guidance Dec. 2016)
- Partner with Patients [patient input]

One More Thing…

Go to www.fda.gov and liberally use ‘Search FDA’



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