Personal Care Products Council
Fall Conference

Food and Drug Administration Program Alignment

What has happened since May 15th…

Alonza Cruse, Director
Office of Pharmaceutical Quality Operations
Office of Regulatory Affairs
Food and Drug Administration

October 25, 2017

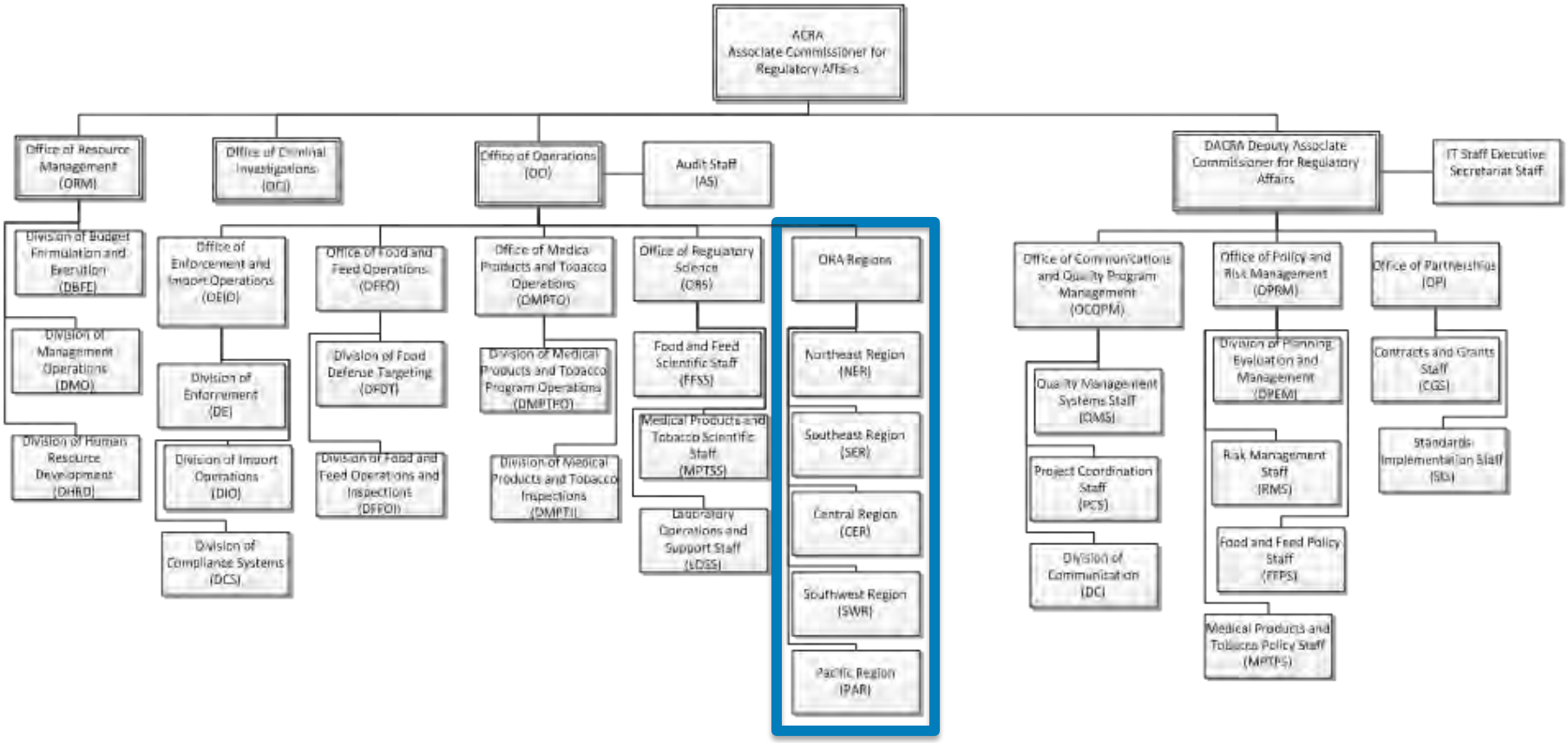
Our Origin Story

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

2013 FDA Program Alignment Charge

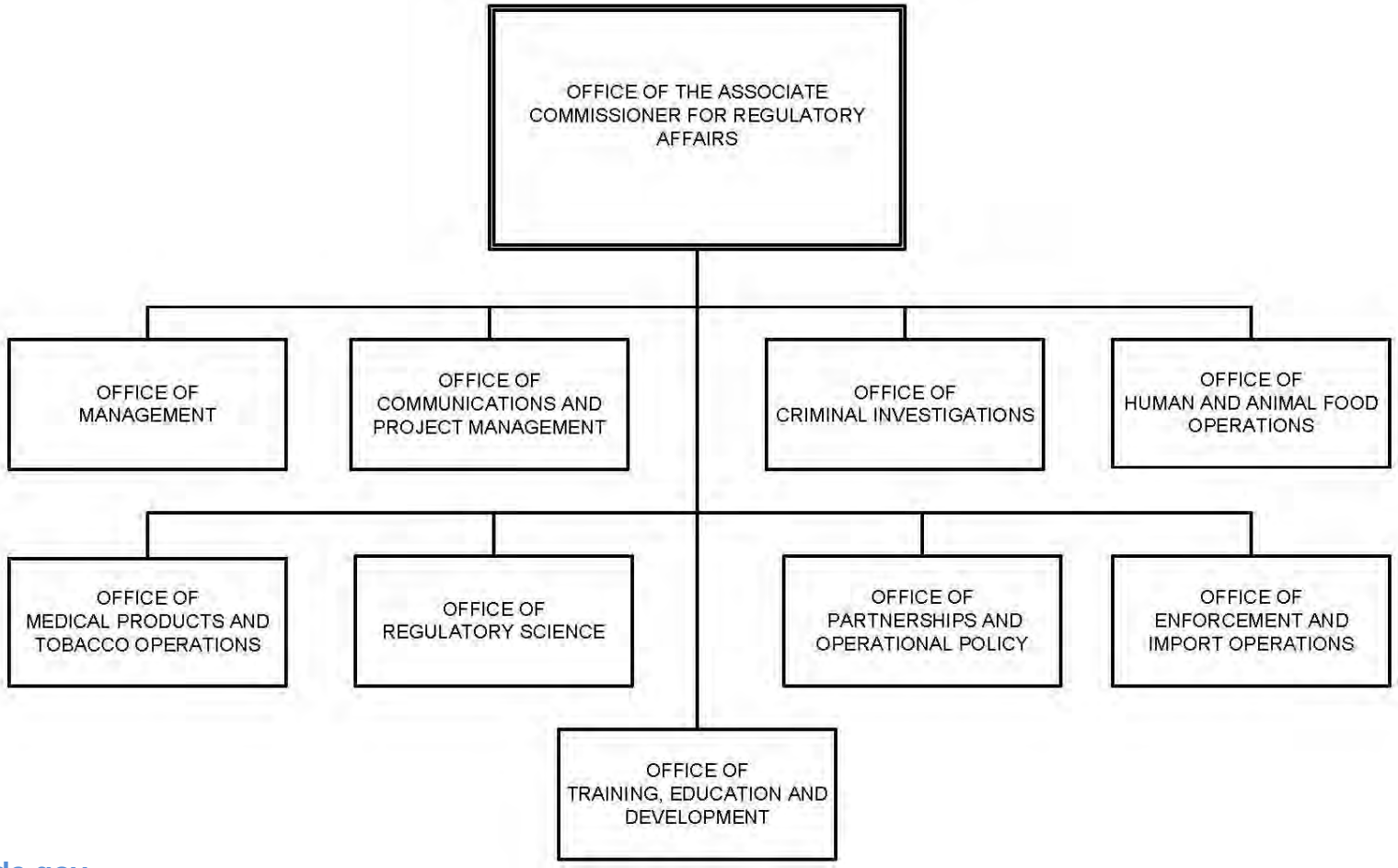
OLD

Geographically Aligned Organizational Model



New

Program Aligned Organizational Model



Program Alignment: Key Changes

From	To
Geographic management of operations	Program management of operations, management teams based on staff: • Bioresearch Monitoring 2 management teams • Biologics 2 management teams • Human and Animal Food 12 management teams • Medical Device and Radiological Health 3 management teams • Pharmaceutical Quality 4 management teams • Tobacco • Plus Imports as a program 5 management teams
SES Regional Food & Drug Directors	SES Program Directors
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

Program Alignment: Key Changes

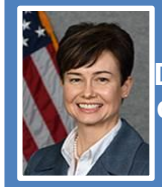
From	To
13 labs reporting into the regions	National Lab Management - 13 labs reporting into ORA's Office of Regulatory Science with three additional directors managing separate program operations
Division of Human Resource Development within the Office of Resource Management	Office of Training, Education and Development
State Cooperative Programs decentralized across five regions – shellfish, milk, retail	Office of State Cooperative Programs under the Human and Animal Food Operations, as a single national program(s)
Functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators	Retain certain functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators
Functions decentralized local reporting: Freedom of Information (FOI) staff, industrial hygienists (IH), and administrative staff	Staff remain embedded locally, but report into a single office: FOI staff report into Division of Information Disclosure; IHs report into the Office of Regulatory Science; administrative staff report into the Office of Management

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

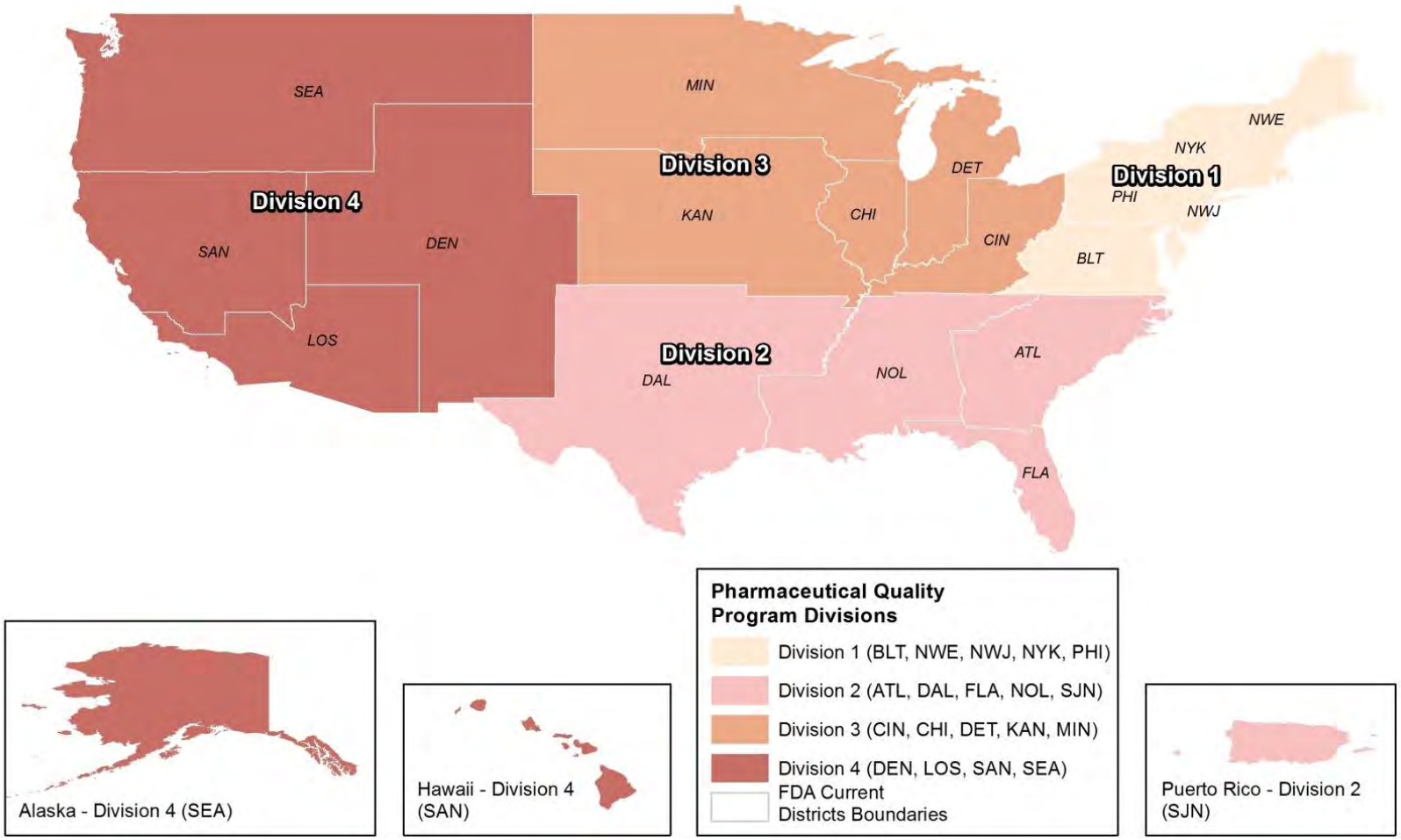
OPQO Office Structure

OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

Alonza Cruse
Director, Office of Pharmaceutical Quality Operations

- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS I
- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS II
- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS III
- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS IV
- DIVISION OF PHARMACEUTICAL QUALITY PROGRAMS
- DIVISION OF FOREIGN PHARMACEUTICAL QUALITY INSPECTIONS

OPQO Boundary Map



Concept of Operations

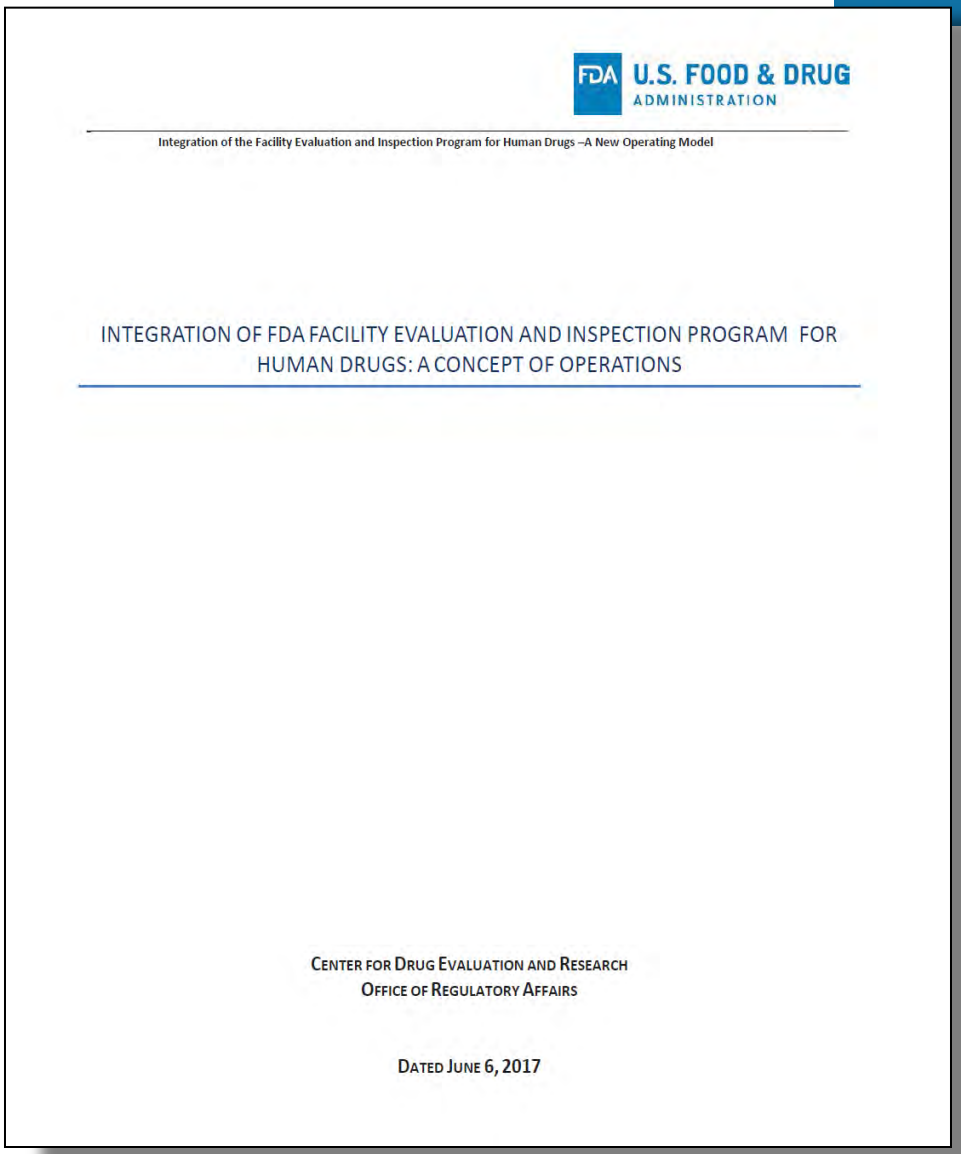
Integration of FDA Facility Evaluation and Inspection Program for Human Drugs

ConOps Agreement

- Covers Pre- and Post-Approval, Surveillance, and For-Cause Inspections at domestic and international drug facilities
- Does not cover compounding, and bioresearch monitoring, and Pre-Approval Inspections for biotech products
- For ORA and CDER staff involved in these inspections, outlines
  - workflow
  - roles and responsibilities (RACI charts;

R: Responsibility; A: Accountability;

C: Consulted; I: Informed)



U.S. FOOD & DRUG ADMINISTRATION

Integration of the Facility Evaluation and Inspection Program for Human Drugs –A New Operating Model

INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF REGULATORY AFFAIRS

DATED JUNE 6, 2017

Why Concept of Operations?

Needs

- Better oversight of increasingly complex and global manufacturing of drugs
- Improved efficiency in line with the ORA Program Alignment into vertically integrated, program aligned areas
- Enhanced IQA approach – alignment/integration between field professionals and review staff
- New commitments and improved coordination and efficiency of work performed under generic drug program as per GDUFA II

Concept of Operations Goals

Goals

- Create and implement a **formalized and streamlined facility evaluation and inspection program** that ensures:
  - Consistency, efficiency, and transparency in facility evaluations, inspections, and regulatory decision-making for marketing applications across the FDA;
  - Strategic alignment across CDER and ORA functional units by clarifying roles and responsibilities;
  - Improved FDA's operational capacity by enhancing collaboration between various CDER and ORA offices;
  - Enhanced quality and increased access to facility and regulatory decisional information across FDA;
  - Improved timelines for regulatory, advisory, and enforcement actions to protect public health and promote drug quality, safety, and effectiveness.

Concept of Operations Goals

Scope

- **All quality inspections** - pre-approval, post-approval, surveillance, for-cause
- **All inspection locations -** domestic and international
- **Development, communication, implementation** of ConOps in
  - CDER
    - OPQ (OPPQ, OPF and OS)
    - OC OMQ
  - ORA
    - Office of Operations
    - Office of Pharmaceutical Quality Operations
    - Office of Medical Products and Tobacco Operations
    - Office of Strategic Planning & Operational Policy

ConOps Highlights

What is new?

- Improved communication with stakeholders
  - decisional letters
  - follow-up engagements
- Defined timelines
- Parity between domestic and international inspections
- Improved collaboration, communication, and information sharing between CDER and ORA
- Streamlined work flow
- Consistent work processes
- Clear roles and responsibilities
- Better use of quality knowledge to support facility evaluations (e.g., site dossiers)

One Agency. One Quality Voice.

“…ensure the Agency’s regulation of pharmaceutical products is a collaborative effort that best meets our public health mission.”

Transmittal email for FDA's FY 2017 Strategic Priorities for the Pharmaceutical Program

Mutual Recognition Agreement

PURPOSE: U.S. and EU regulators will be able to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities.

- Represents culmination of nearly 3 years of FDA/EU cooperation as part of the Mutual Reliance Initiative.
- Will allow FDA and EU to rely upon information from drug inspections conducted within each other's borders.
- Enables FDA and EU to avoid duplication of drug inspections, lower inspection costs and enable regulators to devote more resources to other parts of the world where there may be greater risk.

Resources and Contacts

www.FDA.gov/ORA

- ORA and Program Alignment
- ORA Organization Charts and Boundary Maps
- Fact Sheets
  - OPQO and all operational offices
- Investigations Operations Manual
  - Headquarters, District/Division Contact Information

ORA Contacts

- State and local inquiries
  - District Director/Program Division Directors
  - State Liaison
- General Inquiries
  - engageORA@fda.hhs.gov
- Partnerships
  - OP-ORA@fda.hhs.gov

Thank You

Questions and Discussion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ADMINISTRATION