Update on FDA's Office of Inspections and Investigations

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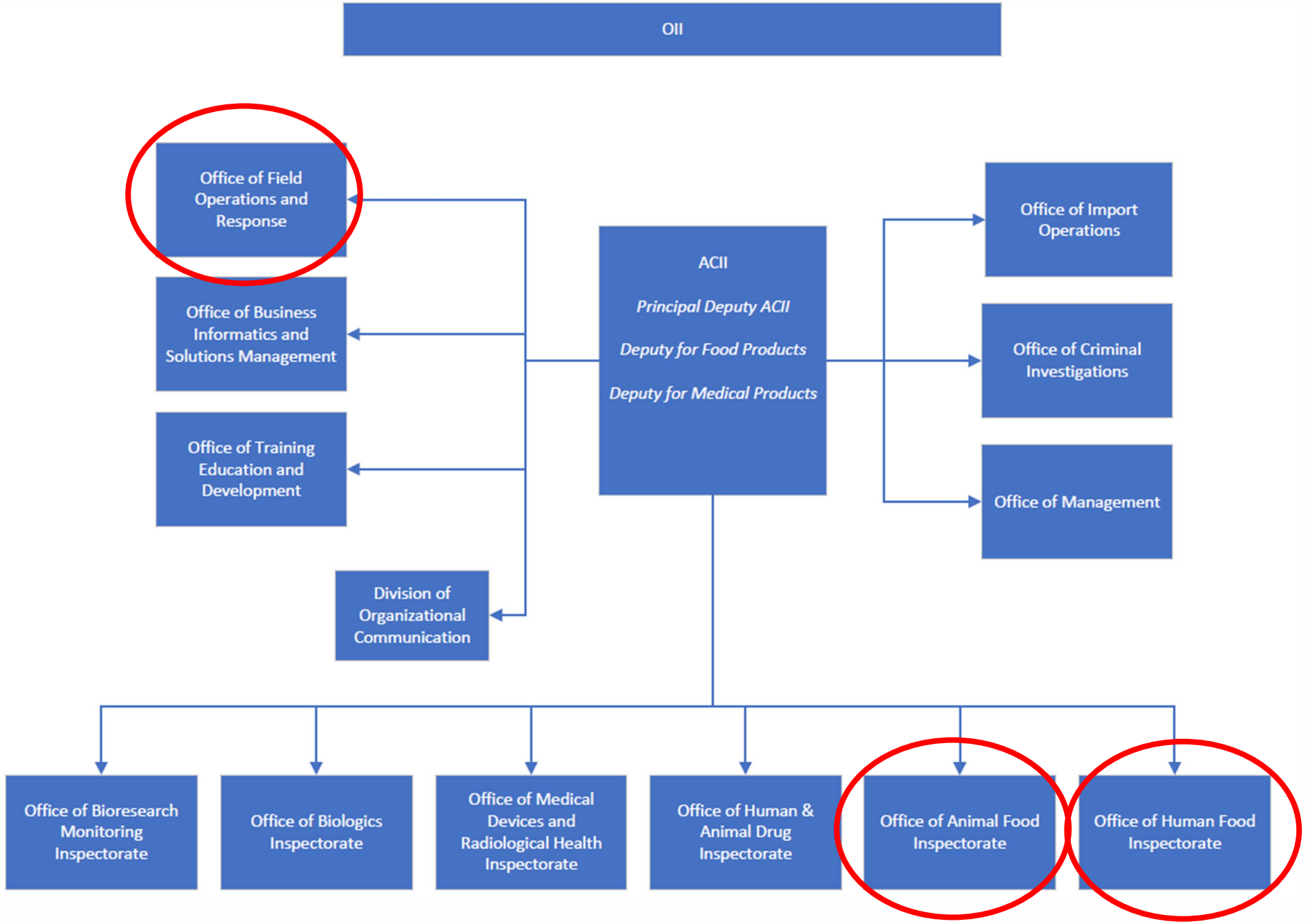
Human Food Inspectorate East 1

OII Acronyms

Acronym	
ACII	Associate Commissioner for Inspections and Investigations
OII	Office of Inspections and Investigations
OHFI	Office of Human Food Inspectorate
OAFI	Office of Animal Food Inspectorate
OFOR	Office of Field Operations and Response
OHFI Central	Office of Human Food Inspectorate Central
OHFI East	Office of Human Food Inspectorate East
OHFI West	Office of Human Food Inspectorate West
OGSHFI	Office of Global and Specialty Human Food Inspectorate
DHFI	Division of Human Food Inspectorate
SSA	Supervisory Senior Advisor


OII
Office of Field Operations and Response
Office of Business Informatics and Solutions Management
Office of Training Education and Development
Division of Organizational Communication
ACII
Principal Deputy ACII
Deputy for Food Products
Deputy for Medical Products
Office of Import Operations
Office of Criminal Investigations
Office of Management
Office of Bioresearch Monitoring Inspectorate
Office of Biologics Inspectorate
Office of Medical Devices and Radiological Health Inspectorate
Office of Human & Animal Drug Inspectorate
Office of Animal Food Inspectorate
Office of Human Food Inspectorate

Reorganization New Model for Field Operations

The Office of Regulatory Affairs (ORA) became the Office of Inspections and Investigations (OII) on October 1, 2024.

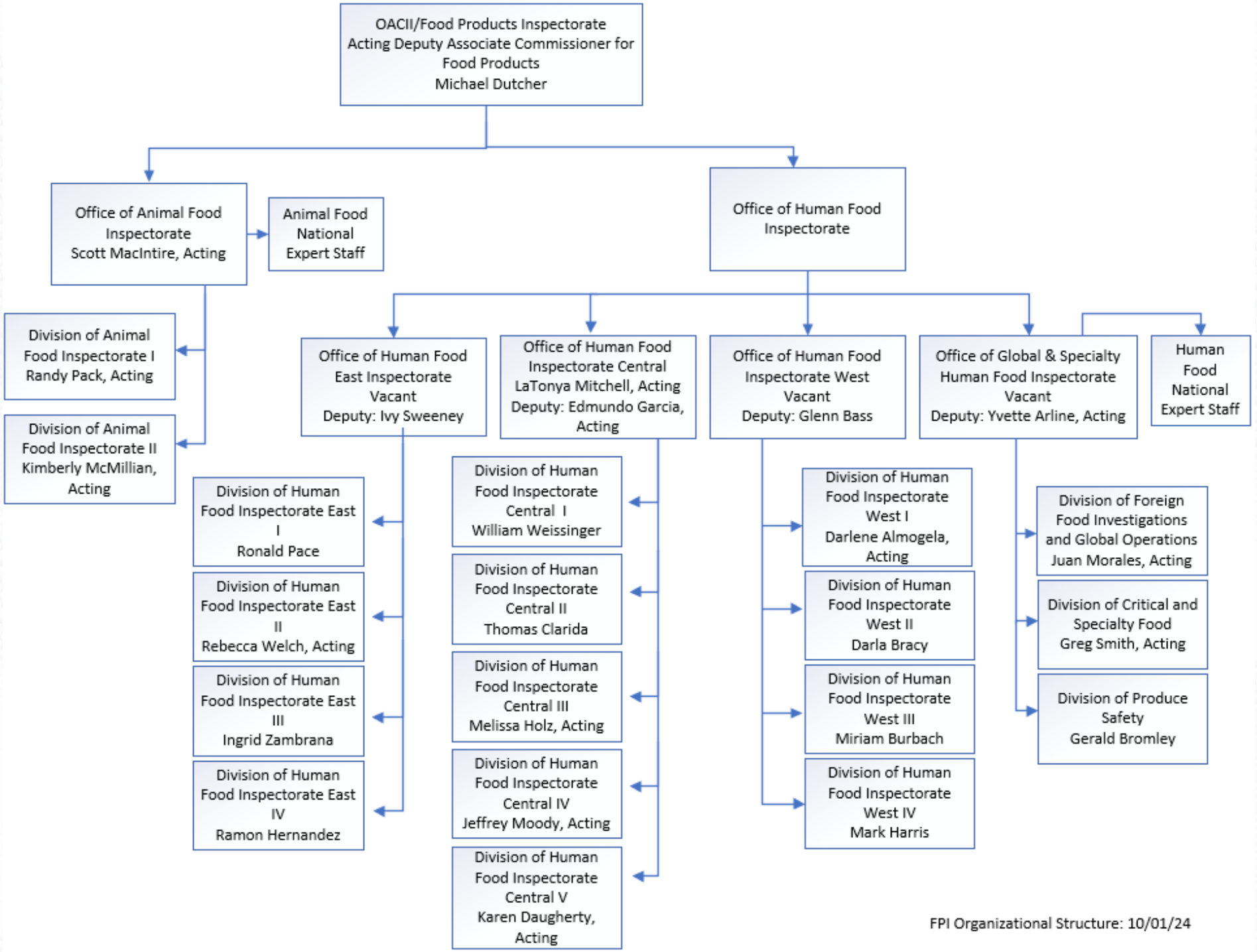
Office of Human and Animal Foods Operations will change names as follows:

- Food Products Inspectorate (FPI – formerly OHAFO)
- Office of Human Food Inspectorate East (OHFIE – formerly OHAFO East)
- Office of Human Food Inspectorate West (OHFIW – formerly OHAFO West)
- Three New Offices
  - Office of Human Food Inspectorate Central (OHFIC)
  - Office of Global and Specialty Human Food Inspectorate (OGSHFI)
  - Office of Animal Food Inspectorate (OAFI)

OHFI and OAFI will have new geographical boundaries

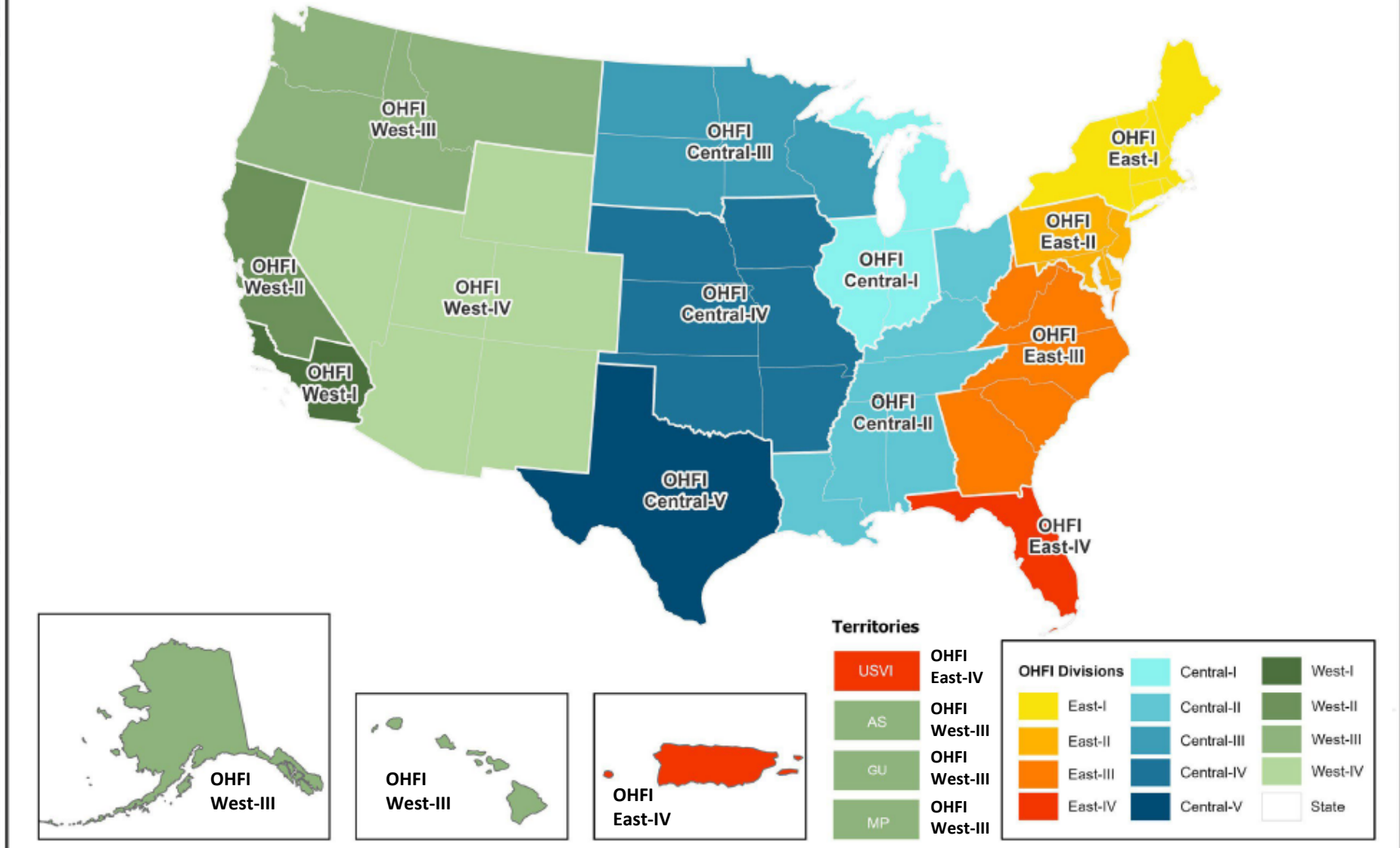
OHFI and OAFI will work closely with Compliance in the Human Food Program (HFP) and Center for Veterinary Medicine (CVM)

Recall Coordinators will continue to have the same responsibilities as pre-reorganization



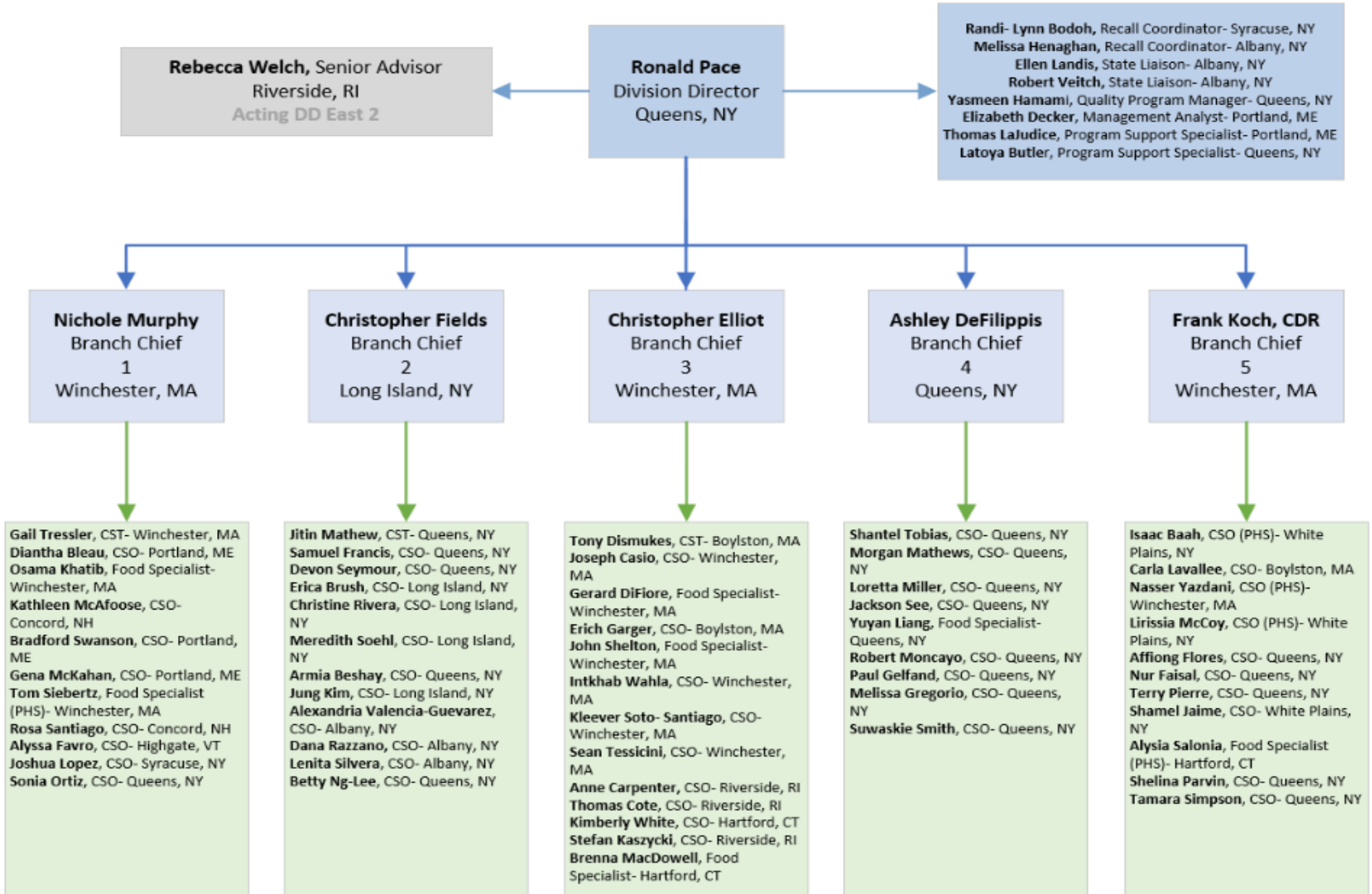
FPI Organizational Structure: 10/01/24

Office of Human Food Inspectorate (OHFI)



Prepared by ORA GIS Program, DAES, 2024

OII HFI East 1 Organizational Chart

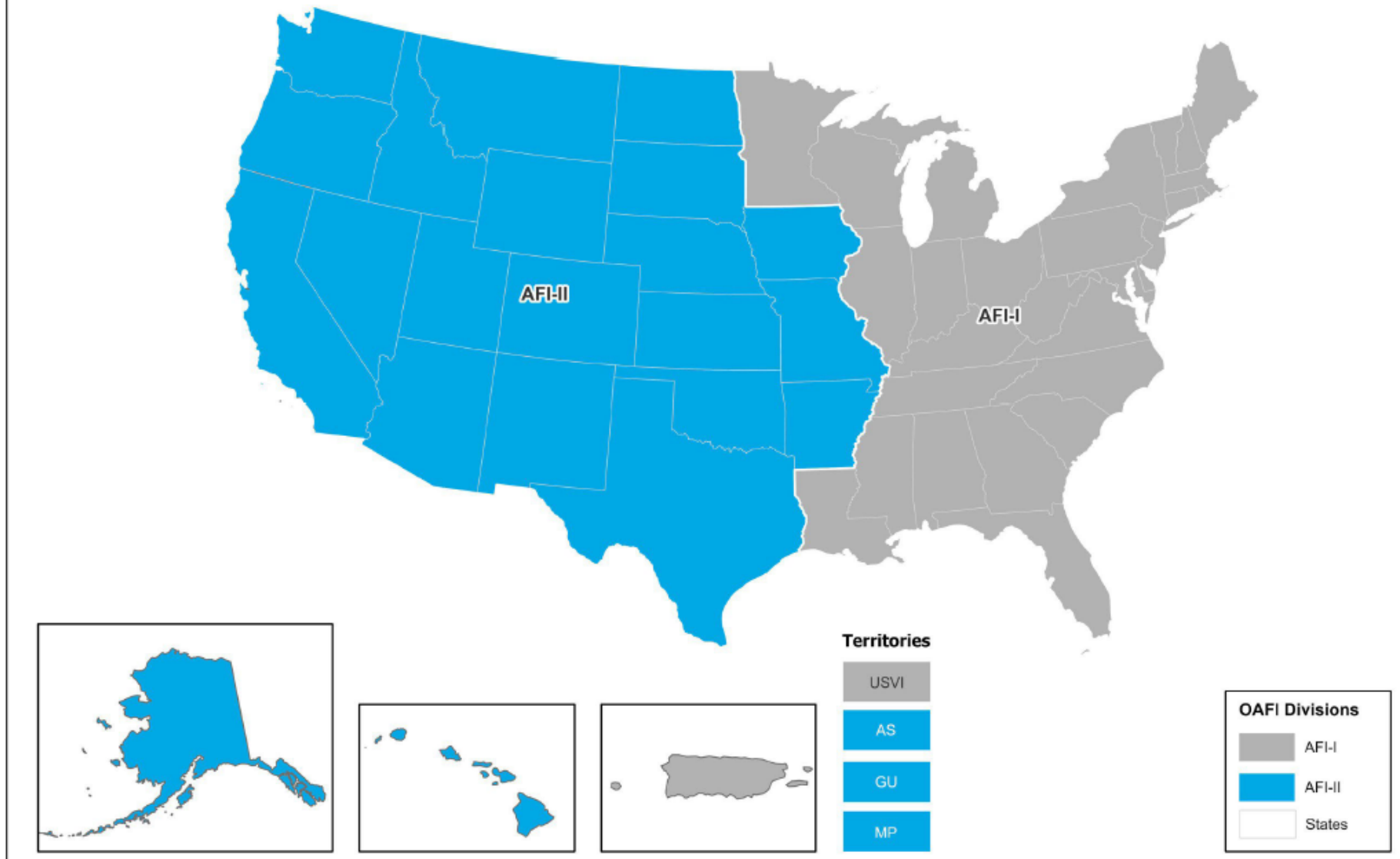


New OII/OHFI Division	Human Food State Liaisons
HFI East 1	Ellen Landis (NY, NH); Rob Veitch (CT, MA, VT, RI, ME)

Office/Division	Recall Coordinators	Recall Email
HFI East 1	Randi-Lynn Bodoh and Melissa Henaghan	oiihfeast1recalls@fda.hhs.gov

Office/Division	ERCs	Coverage Area
OER	Milan McGorty	New York
OER	Kim Langello	CT, MA, ME RI, NH, VT

Office of Animal Food Inspectorate (OAFI)



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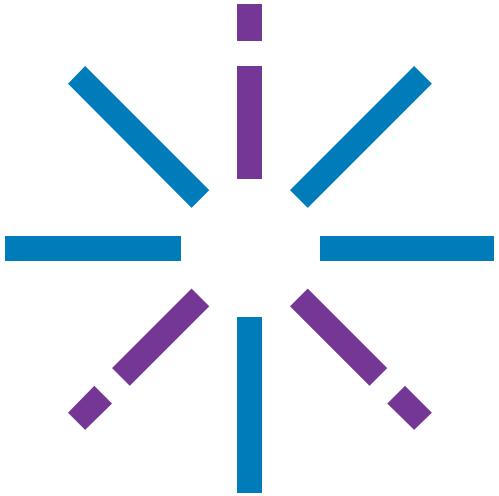
Office of Animal Food Inspectorate (OAFI) Division Boundaries

New OII/OAFI Division	States	Districts
AFI 1	CT, MA, ME, NH, NY, RI, VT, DE, NJ, PA, MD, DC, VA, WV, GA, NC, SC, FL, PR, VI, IL, IN, MI, OH, KY, TN, LA, AL, MS, WI, MN	NWE-DO, NYK-DO, PHI-DO, NWJ-DO, BLT-DO, ATL-DO, FLA-DO, SJN-DO, CHI-DO, DET-DO, CIN-DO, NOL-DO, MIN-DO
AFI 2	ND, SD, IA, KS, MO, NE, AR, OK, TX, CA, AS, GU, MP, HI, AK, ID, MT, OR, WA, AZ, NV, CO, UT, NM, WY	MIN-DO, KAN-DO, DAL-DO, LOS-DO, SAN-DO, SEA-DO, DEN-DO

Office of Animal Food Inspectorate (OAFI) Division State Liaisons

New OII/OAFI Division	Animal Food State Liaisons
AFI 1	William Murray (CT, NJ, MD, PA, VA, WV, NC, DC, DE, MA, ME, NH, NY, RI); Adam Williams (TN, AL, FL, GA, SC, LA, MS, PR, VI); Vacancy (KY, IL, IN, MI, MN, OH, WI)
AFI 2	Alcee Tavarez (MO, NE, TX, AR, OK); Julie Vosilus (IA, KS, SD, WY); Suzanne Crotty, Acting (NM, CO, UT, ID, MT, NV, AZ); Lisa Nakagawa (ND, CA, WA, GU, HI, OR)

Office of Field Operations and Response



Office of Field Operations and Response

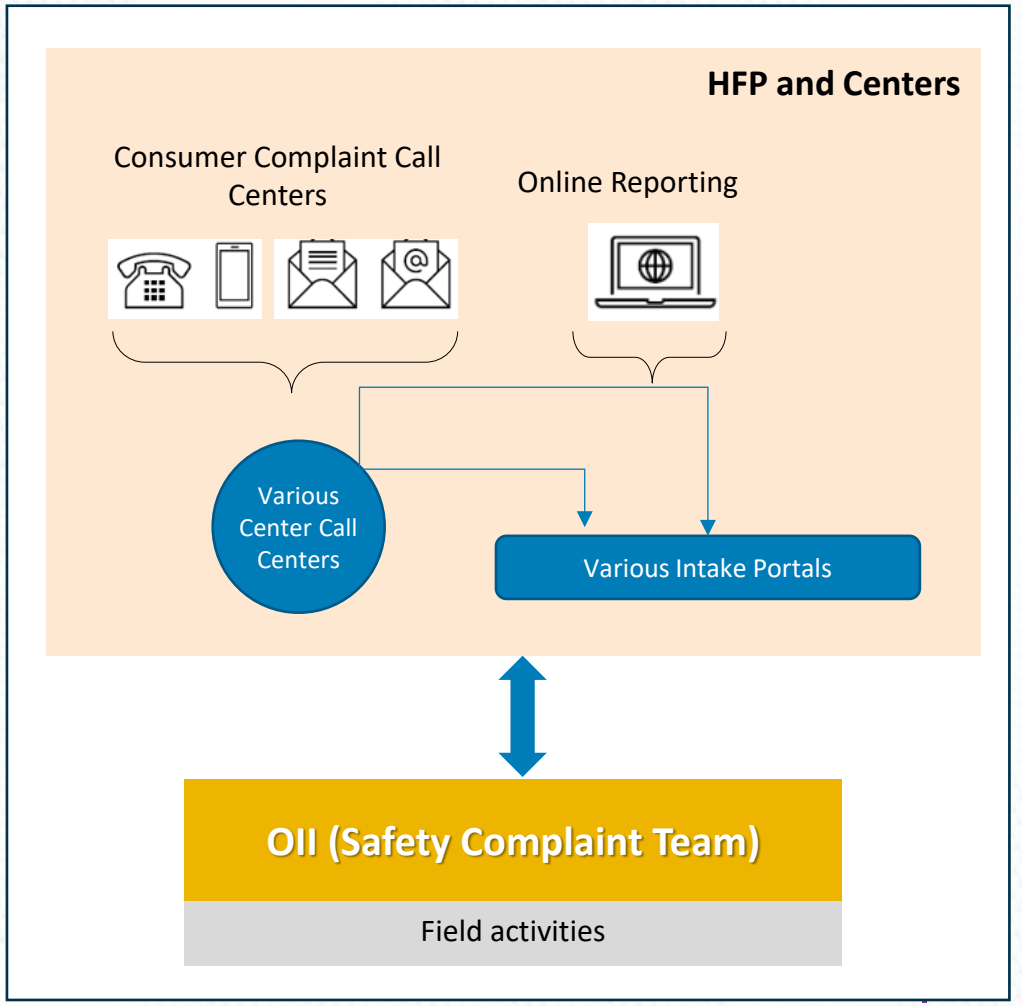
Office of Emergency Response (OER)

- ERCs will continue to cover the same States as pre-reorganization
- ERCs will continue to have close relationships with their local and State counterparts (including RRTs)
- ERCs will continue to have close relationships with all OII program areas as well as CORE.
- Consolidated emergency coordination leadership structure
- Emergency.operations@fda.hhs.gov

FDA's New Complaint Handling Approach

The FDA is streamlining its handling of consumer complaints to be more efficient and responsive to public health concerns.

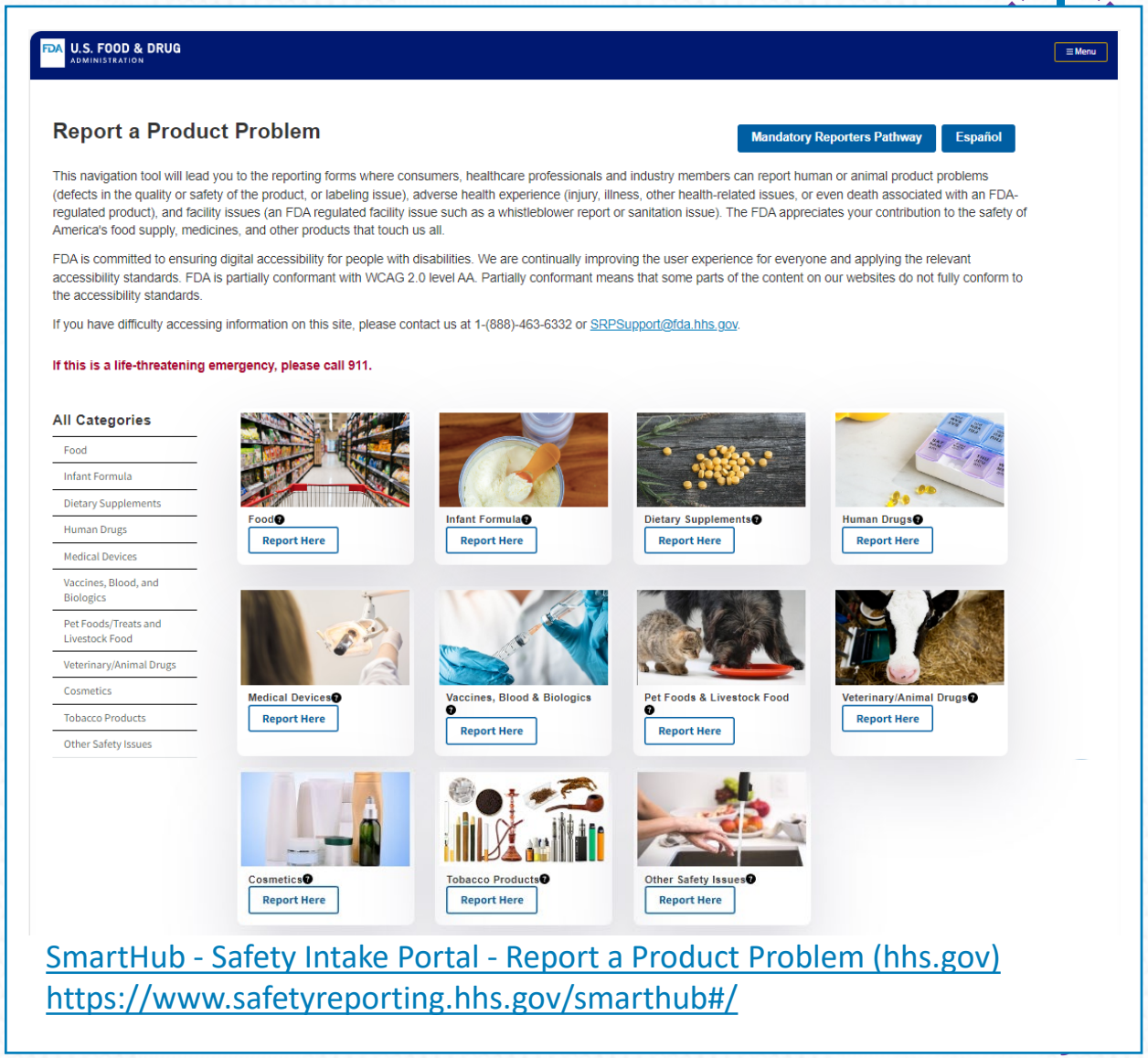
- HFP and Centers will be responsible for the intake, evaluation, and triage of consumer complaints and inquiries.
- HFP and Centers will refer complaints to OII to collaborate on field follow-up activities as needed.



How Should Consumers Submit a Complaint?

- Consumers wishing to submit a complaint directly to FDA should be directed to the new ***SmartHub*** or call 1-888-INFO-FDA (1-888-463-6332).
  - ***Action***: Please make sure all your agency's ***public-facing*** webpages and materials are updated accordingly.

- All prior ORA Consumer Complaint Coordinators numbers and dedicated complaint email boxes will be decommissioned. Calls will be routed to 1-888-INFO-FDA and the prior email boxes will not be monitored.



SmartHub - Safety Intake Portal - Report a Product Problem (hhs.gov)
https://www.safetyreporting.hhs.gov/smarthub#/

How Should SLTT Partners Forward Complaints?

- SLTT partners should forward complaints directly to FDA using these email addresses.
  - ***Action***: Please make sure all your ***internal protocols only*** are updated with this information accordingly.

- If you have any problem or concern, notify the ***FDA National Consumer Complaint Coordinator*** at NCCCComplaints@fda.hhs.gov

Human Foods & Dietary Supplements
HFPComplaints@fda.hhs.gov

Vaccines, Blood, Cell and Gene Therapies
OCOD@fda.hhs.gov

Human Drugs
DrugInfo@fda.hhs.gov

Human Medical Devices
CDRHDeviceAllegations@fda.hhs.gov

Veterinary Drugs, Devices and Foods
AskCVM@fda.hhs.gov

Tobacco Products
AskCTP@fda.hhs.gov

Cosmetics
OCSComplaints@fda.hhs.gov

How Will the Complaint Response be Coordinated?

- If SLTT partners forward a complaint, HFP and the Centers may follow up directly with you or the complainant for more information.
- If FDA decides that field activities are needed, OII's new Safety Complaint Team (SCT), OII Inspectorates, and/or CORE Team will coordinate with all the appropriate FDA groups, including relevant FDA state liaisons and emergency response coordinators. FDA state liaisons will involve state counterparts, as necessary.
- HFP will share milk/dairy and molluscan shellfish related complaints with the Milk/Shellfish specialists in the Office of Microbiological Food Safety. The Milk/Shellfish specialists will continue to share the complaints with the States under the cooperative agreement.

Questions