Association for Accessible Medicines GRx + Biosims 2024

Medical Products Inspectorates Keynote Address:

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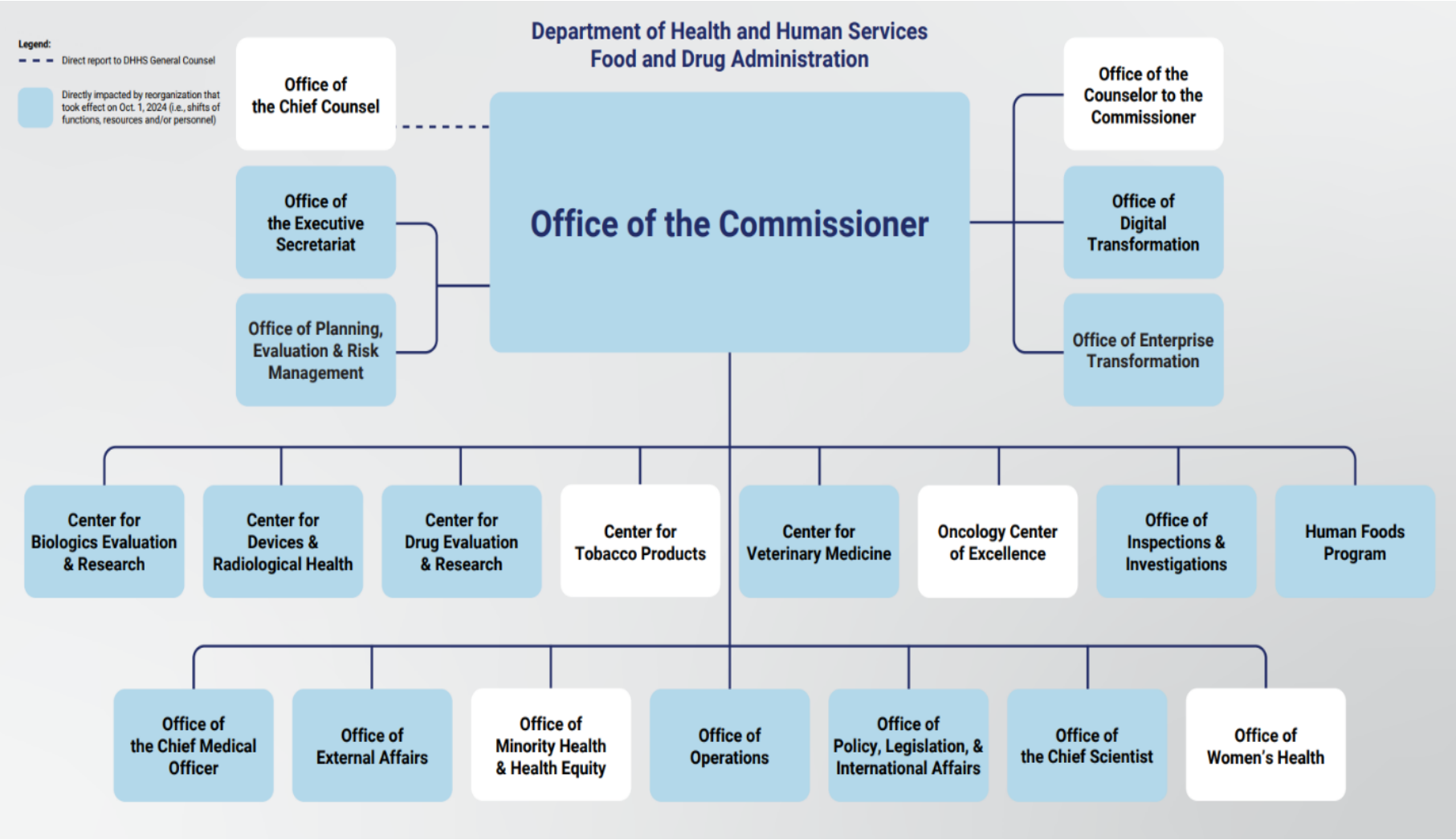
October 22, 2024

Key Topics

- FDA Reorganization
- OII Core Mission
- Inspection Trends
- Current Initiatives
  - FUIP
  - MRA
  - ETAM
- FY25 Priorities

FDA Modernization – A New Model



U.S. FOOD & DRUG ADMINISTRATION

FDA Organization Chart – Office of Inspections and Investigations (OII)

Effective Oct. 1, 2024

Legend:

Directly impacted by reorganization that took effect on Oct. 1, 2024 (i.e., shifts of functions, resources and/or personnel)

Department of Health And Human Services
Food and Drug Administration
Office of Inspections and Investigations

Associate Commissioner for Inspections and Investigations

Office of Field Operations & Response

Organizational Quality Staff

Office of Emergency Response
Office of Field Regulatory Operations†

Office of Business Informatics & Solutions Management

Division of Regulatory Business Informatics & Solutions
Division of Import Business Informatics & Solutions
Division of Solutions Planning, Management & Governance
Division of Work Planning & Analytics

Office of Training Education & Development

Division of Instructional Systems & Technology
Division of Multi-Program, Leadership & Management Training
Division of Programmatic Training

Office of Import Operations

Division of Targeting & Analysis
Division of Import Operations
Division of Analysis and Program Evaluation
Division of Southwest Imports
Division of Planning & Public Response
Division of Southeast Imports
Division of Northeast Imports
Division of Northern Border Imports
Division of West Coast Imports

Office of Criminal Investigations

Chicago Field Office
Metro-Washington Field Office
New York Field Office
Los Angeles Field Office
Miami Field Office
Kansas City Field Office

Office of Management

Office of Budget, Facilities & Travel Support
Office of Workforce Management

Office of Bioresearch Monitoring Inspectorate

Division of Bioresearch Monitoring Inspectorate (I-IV)
Division of Bioresearch Monitoring Global Operations

Office of Biologics Inspectorate

Biologics Global Operations Staff

Division of Biologics Inspectorate (I-III)
Division of Biotechnology Inspectorate

Office of Medical Devices & Radiological Health Inspectorate

Division of Medical Device & Radiological Health Inspectorate (I-IV)
Division of Mammography & Radiological Health Inspectorate
Division of Medical Device & Radiological Health Global Operations

Office of Human & Animal Drug Inspectorate

Division of Human & Animal Drug Inspectorate (I-VI)
Division of Human & Animal Drug Foreign Inspectorate
Division of Human & Animal Drug Global Operations

Office of Animal Food Inspectorate

Division of Animal Food Inspectorate (I-II)

Office of Human Food Inspectorate‡

Office of Human Food East Inspectorate
Office of Human Food Central Inspectorate
Office of Human Food West Inspectorate
Office of Global & Specialty Human Food Inspectorate

†Includes Division of Tobacco Inspectorate
‡Includes specialized teams for products such as infant formula

New Model for Field Operations

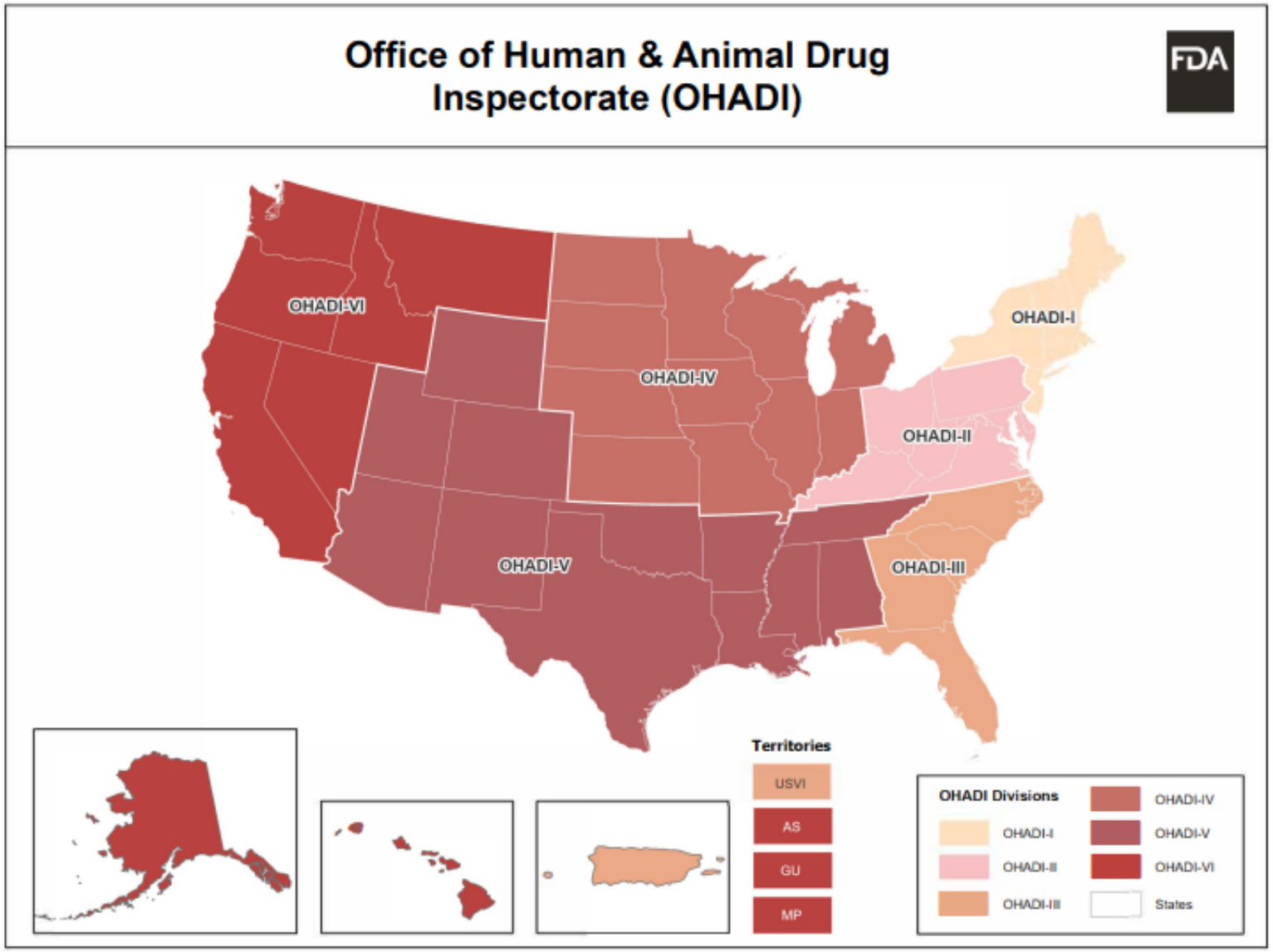
- Streamlined decision making
- Improved coordination
  - inspections
  - compliance
  - emergency management
- Modernization and strengthening collaborations across Agency.

What Changed?

- Compliance functions realigned to FDA Centers and Human Foods Program (HFP)
  - No compliance branches in OII
  - DRCs will now report to inspectorates
- Inspection resources with aligned with center and program priorities
- Consumer complaint intake responsibility FDA Centers and HFP
- The Office of Emergency Response (OER) was moved into OII
- ORA Labs:
  - Food labs to HFP
  - Medical Product Labs to Office of Chief Scientist
- Geographic boundaries realigned

Boundary Maps

Medical Products Inspectorates


Office of Human & Animal Drug Inspectorate (OHADI)
FDA
OHADI-VI
OHADI-IV
OHADI-I
OHADI-II
OHADI-V
OHADI-III
Territories
USVI
AS
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MP
OHADI Divisions
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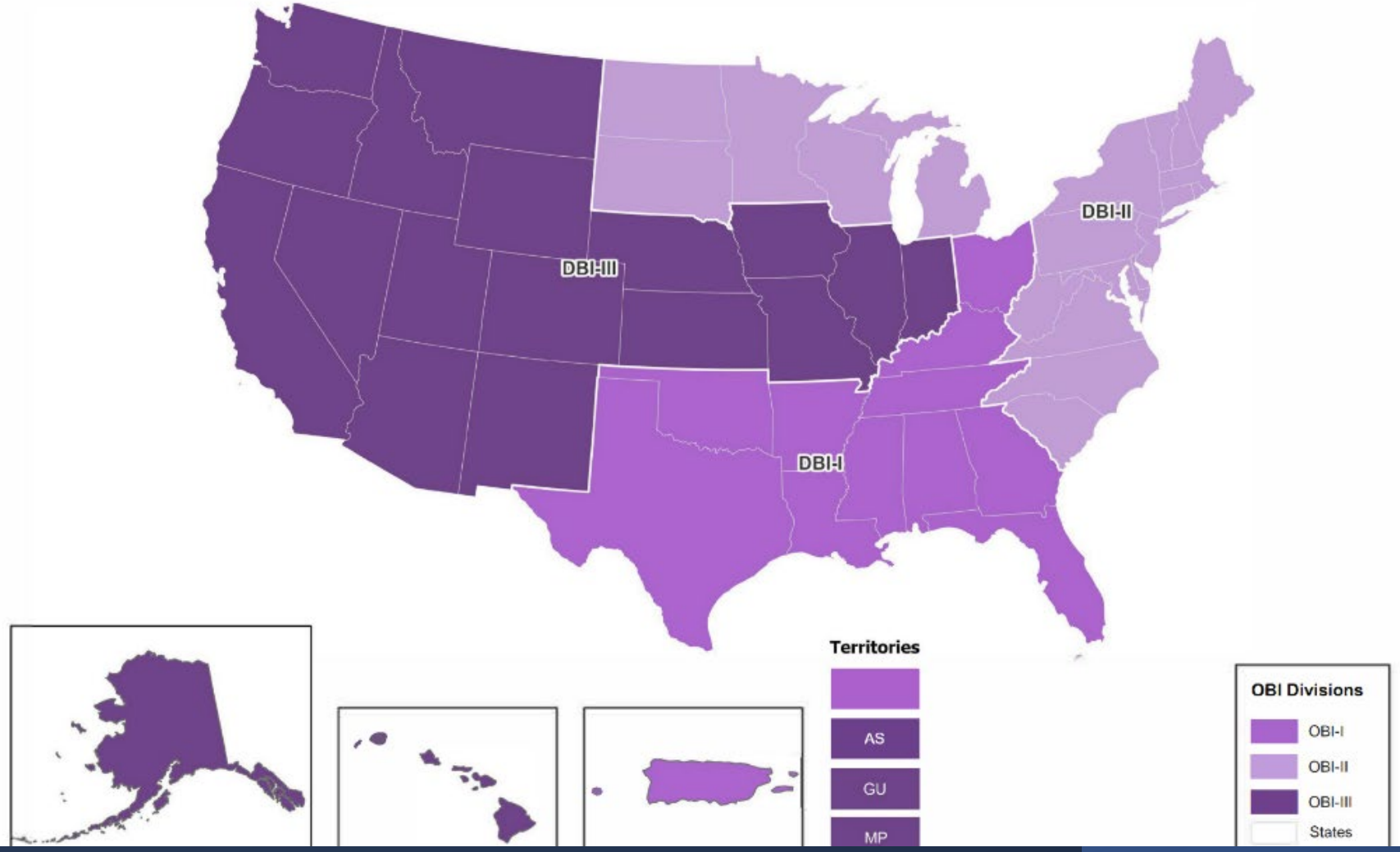
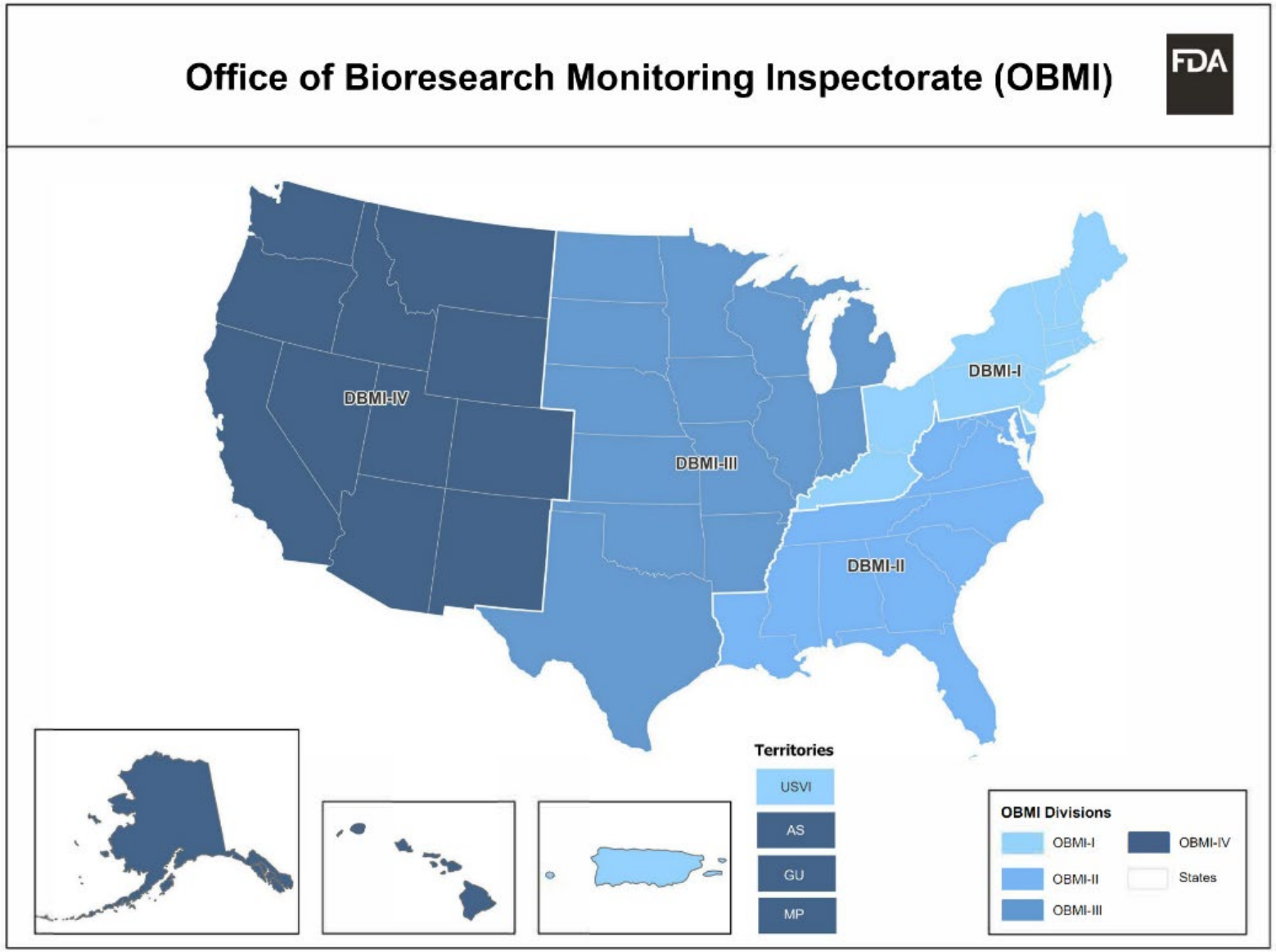
OHADI-III
OHADI-IV
OHADI-V
OHADI-VI
States

Office of Biologics Inspectorate (OBI)




Office of Bioresearch Monitoring Inspectorate (OBMI)
FDA
DBMI-IV
DBMI-III
DBMI-I
DBMI-II
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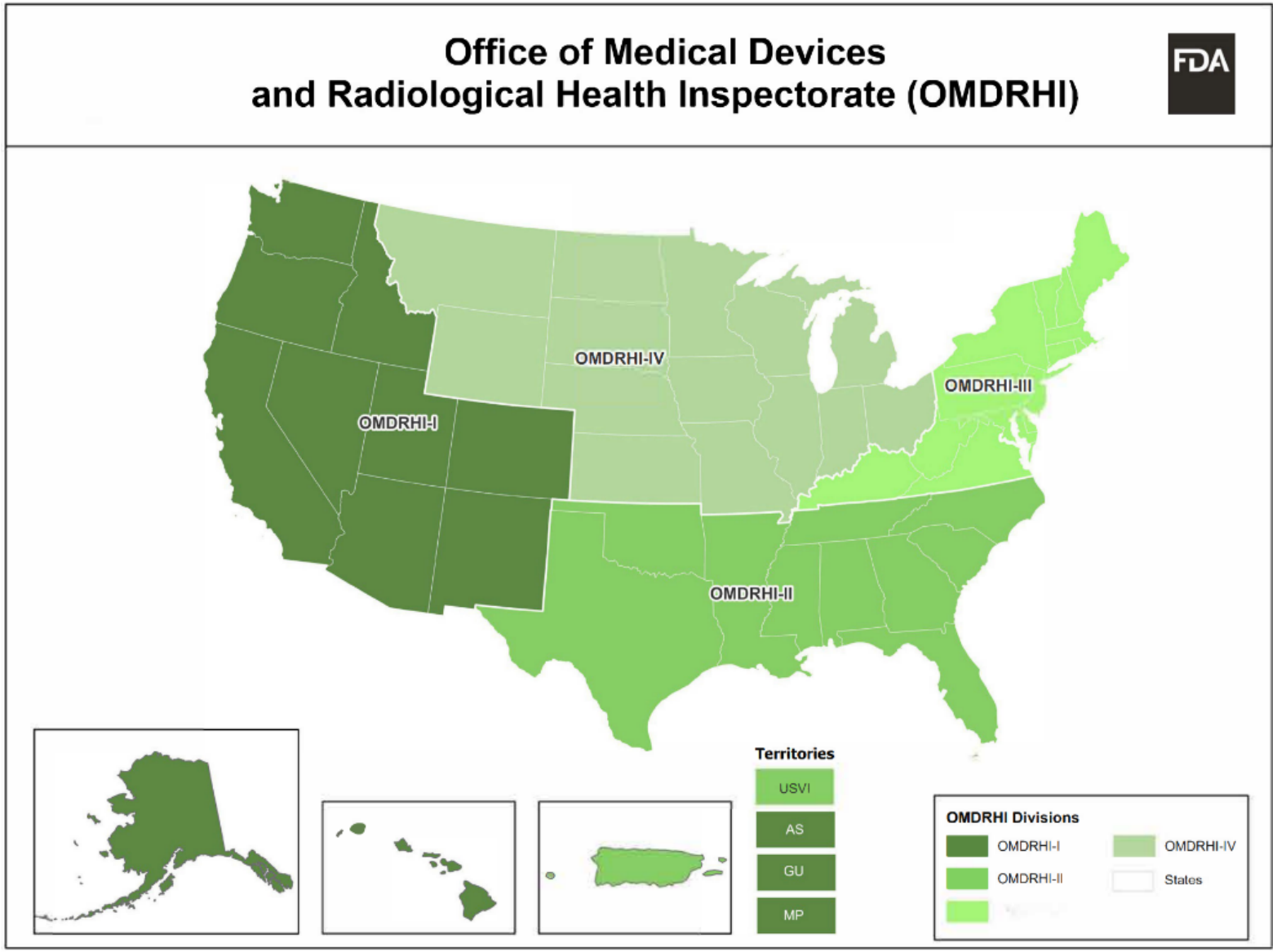
OBMI Divisions
OBMI-I
OBMI-II
OBMI-III
OBMI-IV
States


Office of Medical Devices
and Radiological Health Inspectorate (OMDRHI)
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OMDRHI-III
OMDRHI-I
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Territories
USVI
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MP
OMDRHI Divisions
OMDRHI-I
OMDRHI-II
OMDRHI-IV
States

OII Core Operations

INSPECTIONS

INVESTIGATIONS

IMPORTS

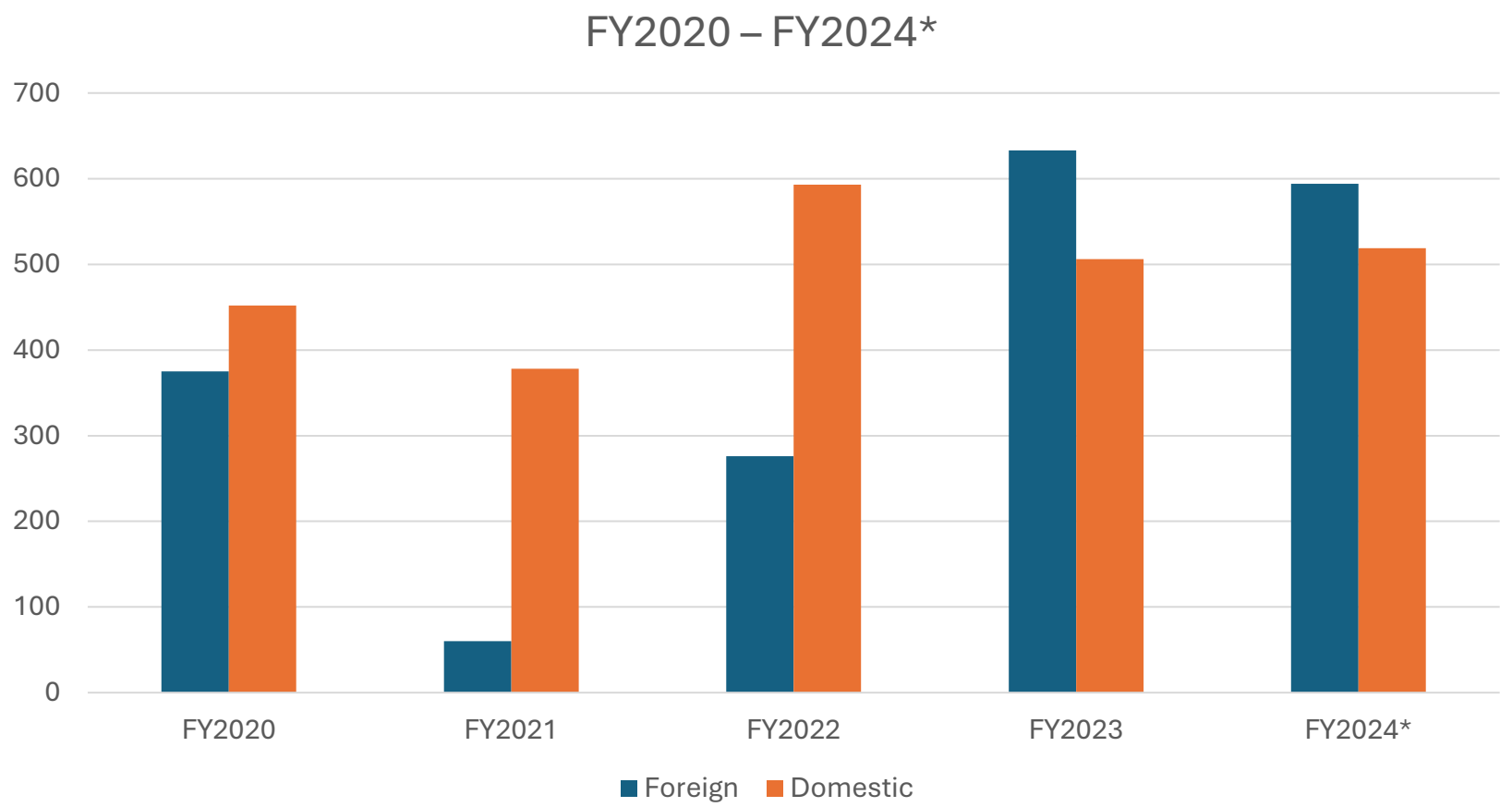
Inspection Accomplishments and Trends

FY2020 – FY2024

Building Public Trust Through Communication & Transparency

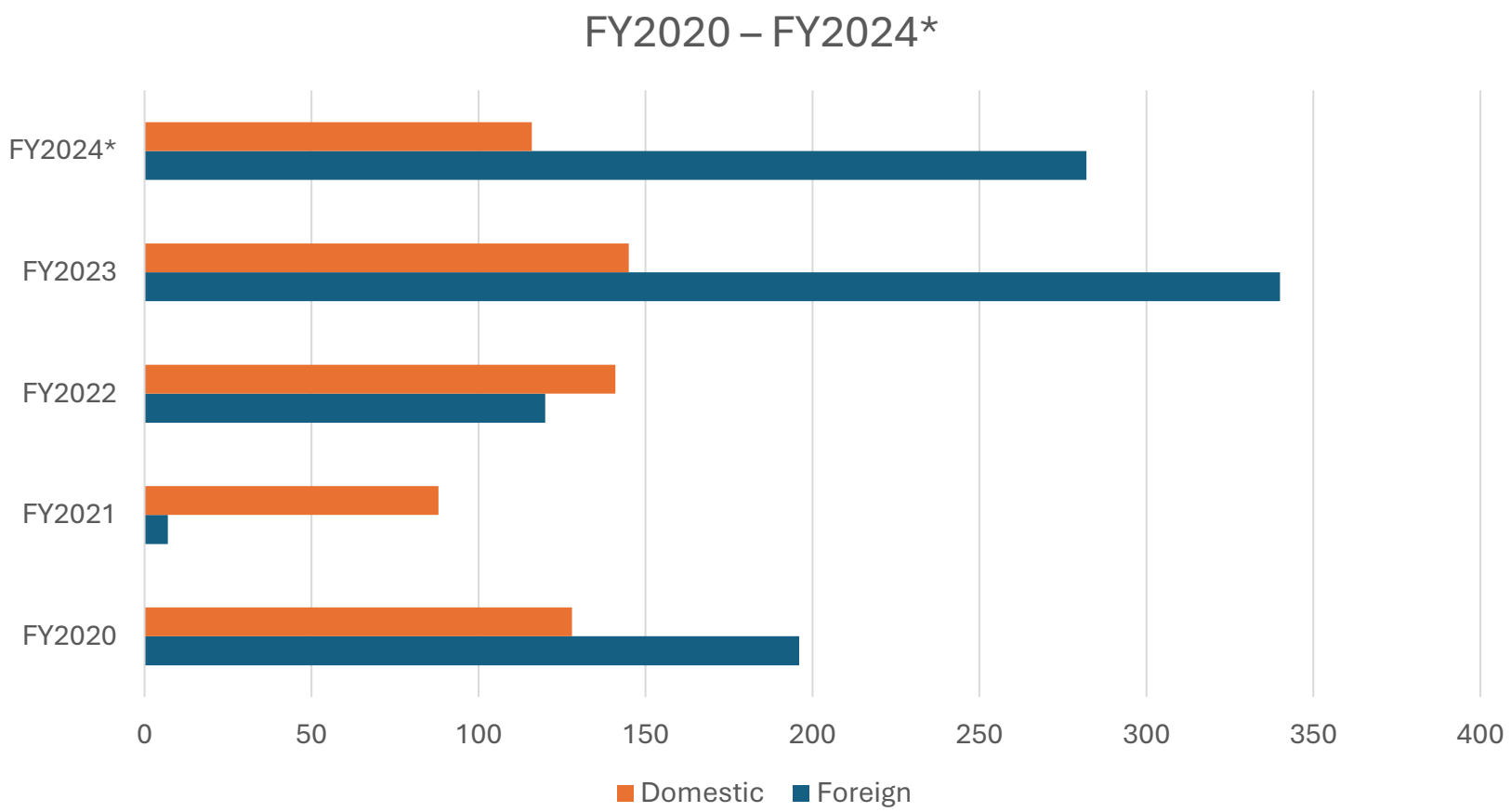
- Trust in the FDA is built on past performance and ongoing commitment to scientific rigor and transparency. Our investigators are committed to facts, science, and the rules governing public health safety.
- Clear communication about FDA decisions, the reasoning behind them, and any corrective actions firms must take helps build and maintain trust with the public and industry.
- In FY23:
  - **87%** of final facility classification letters were issued within 90 days
  - **85%** of regulatory actions completed within 6 months

Pharmaceutical Inspections



***FY24 data through 10/9/2024**

Generic Drug Inspections



***FY24 data through 10/9/2024**

Current Initiatives

Medical Products Inspectorate

Foreign Unannounced Inspection Pilot

Scope	Pharmaceutical Inspections in India and China
Implementation	Three phases to support FDA decision-making
Timeline	Launched in India in March 2022, and in China in July 2023

Medical Products International Program

- Mutual Recognition Agreements
  - EU Human and Vet Drugs
  - Switzerland
- Pharmaceutical Inspectorate Cooperation Scheme (PIC/S)

Emerging Technologies and Advanced Manufacturing

- CDER FRAME
  - Continuous manufacturing
  - Artificial intelligence
  - Distributed manufacturing
  - Point-of-care manufacturing
- CDER Emerging Technologies Program

- Internal/external engagement
  - FDA's Advanced Manufacturing technologies Working Group (AMTWG)
  - CDER's Advanced Manufacturing Research Facility (AMRF)
  - NGO

FY25 Priorities

MAXIMIZE IMPACT IN THE NEW OII

STRENGTHEN OII WORKFORCE

CORE OPERATIONS

EXPANDING PARTNERSHIPS

Thank you.