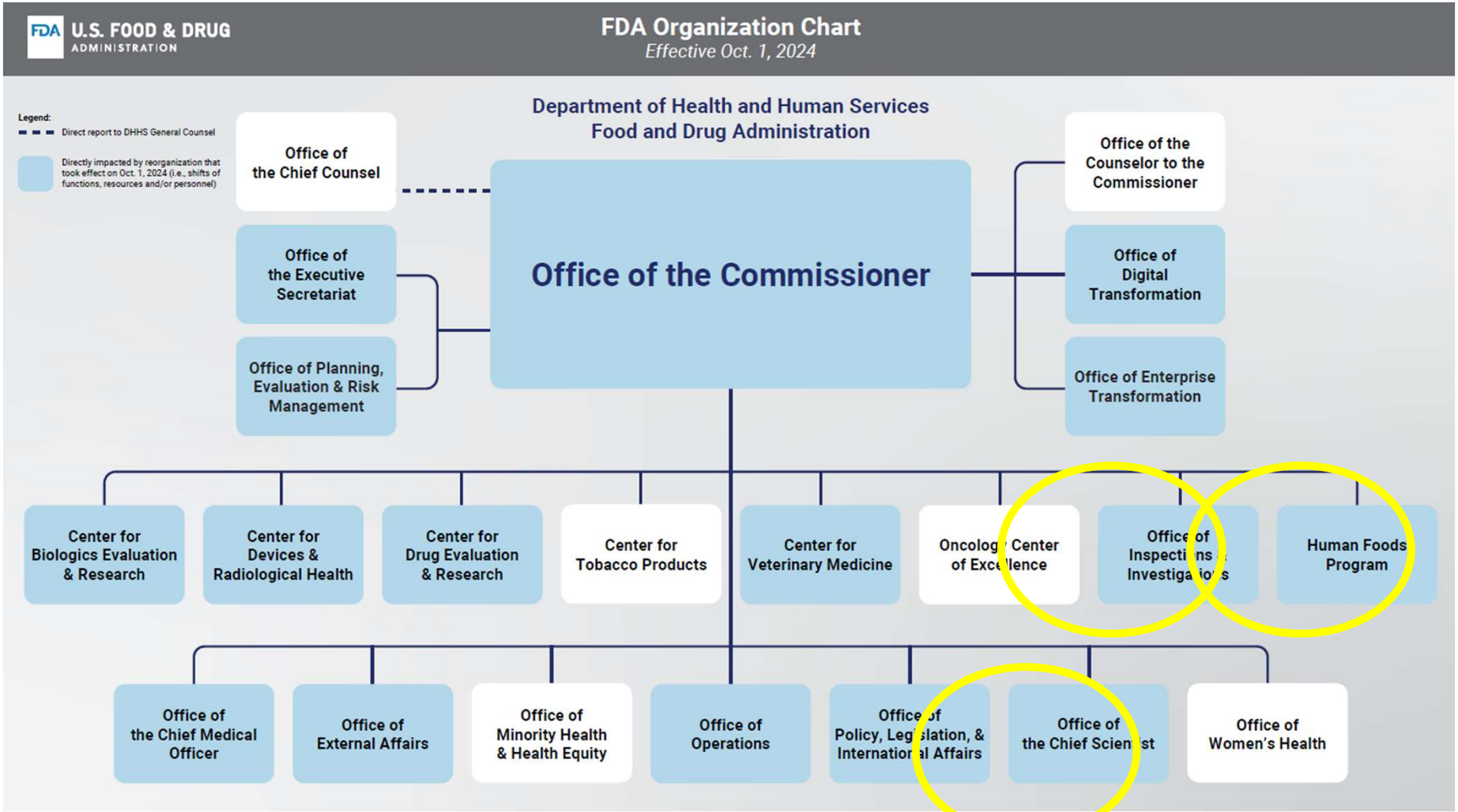
Modernization, Where Are We?

Dan Solis, FDA
Assistant Commissioner for Import Operations


U.S. FOOD & DRUG ADMINISTRATION
FDA Organization Chart
Effective Oct. 1, 2024
Legend:
Direct report to DHHS General Counsel
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 the Chief Counsel
Office of the Executive Secretariat
Office of Planning, Evaluation & Risk Management
Office of the Commissioner
Office of the Counselor to the Commissioner
Office of Digital Transformation
Office of Enterprise Transformation
Center for Biologics Evaluation & Research
Center for Devices & Radiological Health
Center for Drug Evaluation & Research
Center for Tobacco Products
Center for Veterinary Medicine
Oncolog Center of Exc lence
Office of Inspecti ns Investiga ions
Human Foods Program
Office of the Chief Medical Officer
Office of External Affairs
Office of Minority Health & Health Equity
Office of Operations
Office of Policy, Leg slation, & Internatio al Affairs
Office of the Chief Scien ist
Office of Women's Health

Updates- FDA

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

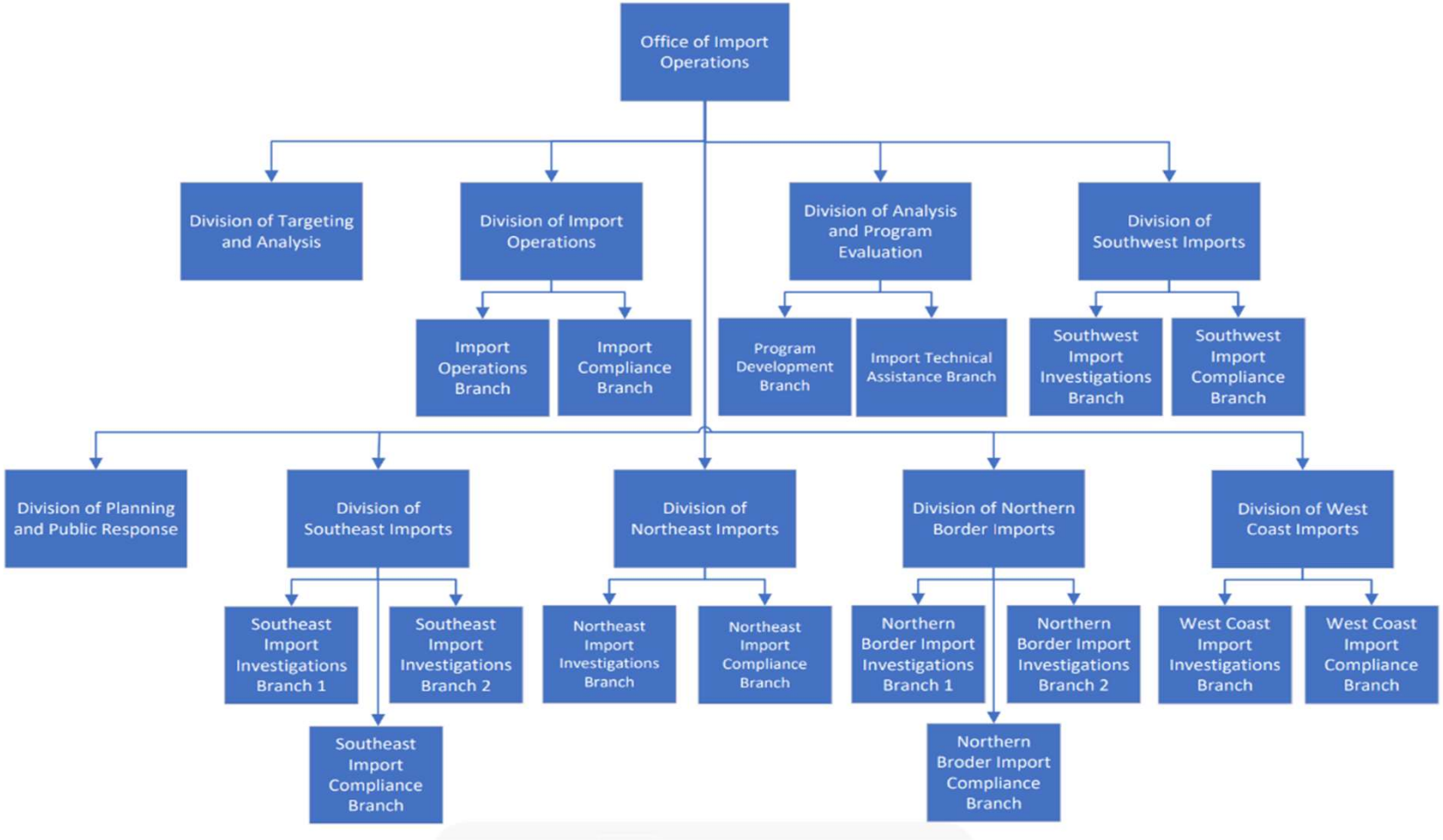
Division of Animal Food Inspectorate (I-II)

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*

Updates:
Office of Import Operations (OIO)



DIVISION OF TARGETING AND ANALYSIS

Harnessing intelligence, advanced technology, and comprehensive risk analytics to target import shipments of FDA regulated commodities which pose a threat to the health, safety, and security of the American public.

Data Analysis and Intelligence Research for risk-informed decision-making.

Receives and reviews Prior Notice and intelligence data

Develop methods for threat analysis, workplanning and resource allocation.

Recommends compliance actions for violations Prior Notice regulation.

Supply Chain Analysis

A liaison to Law Enforcement Agencies for the FDA.

Global Business Identifier (GBI)

In its current design, the GBI test is intended to:

- ✓ Examine the potential for identifiers to improve supply chain visibility and traceability
- ✓ Allow for more efficient customs procedures to expedite legitimate trade
- ✓ Support more secure, streamlined, cost-effective trade operations
- ✓ Operate within the Automated Commercial Environment (ACE) platform
- ✓ Enable volunteer trade participants to submit one or more global entity identifiers for the manufacturer, shipper, seller, exporter, distributor, and packager via the Automated Broker Interface (ABI)

Potential Benefits

- **Streamlined Facilitation –** better assess and identify lower risk and highly compliant firms and products
- **Secure Supply Chains** – helps authenticate and verify supply chains assisting entities in managing risk
- **Whole-of-Customs Coordination** – PGAs can better harmonize risk decision-making across 1USG
- **Shape the Future of GBI-Enabled Traceability** – trade participation will inform the evolution of the GBI test, which seeks enhancements to better meet trade and 1USG's supply chain traceability needs

Global Business Identifier (GBI)

- Progress to date:
  - In 2023, FDA partnered with CBP in co-leading the GBI test to jointly explore how identifiers could be leveraged to reduce redundancies
  - Continue to collaborate in evaluating GBI data elements to determine feasibility of a unique identifier solution to improve 1USG's ability to identify higher-risk shipments and facilitate legitimate trade
  - Continue to assess the impact of identifiers on efficiencies for both trade and PGAs

Entity Identifier Name	Entity Identifier Owner
Legal Entity Identifier (LEI) 20-digit, alphanumeric identifier with underlying reference data elements unique to a legal entity. Over 2.2 million LEIs issued worldwide.	GLEIF Enabling global identity Protecting digital trust
Global Location Number (GLN) 13-digit numeric identifier with varying sets of underlying reference data elements that are customizable to location, function, and operations. Over 2 million companies utilize GS1 Standards.	GS1®
Data Universal Numbering System (DUNS) 9-digit numeric and non-indicative identifier that identifies unique business establishments with a library of over 200 reference data elements. Over 300 million DUNS issued worldwide.	dun & bradstreet

Silicon Valley Innovation Project (SVIP)

- Objectives
  - Collaborate with CBP in adopting interoperability standards, facilitate legitimate trade, accepting data from traditional and non-traditional actors via testing data exchange and messaging using verifiable credentials
- Purpose
  - Align FDA's data needs with CBP's technological advances for seamless, secure transactions
  - Showcase thought leadership in streamlining the import process by improving verification of supply chains
  - Explore supply chain transparency and compliance with FDA's Food Traceability Rule

Silicon Valley Innovation Program (SVIP)

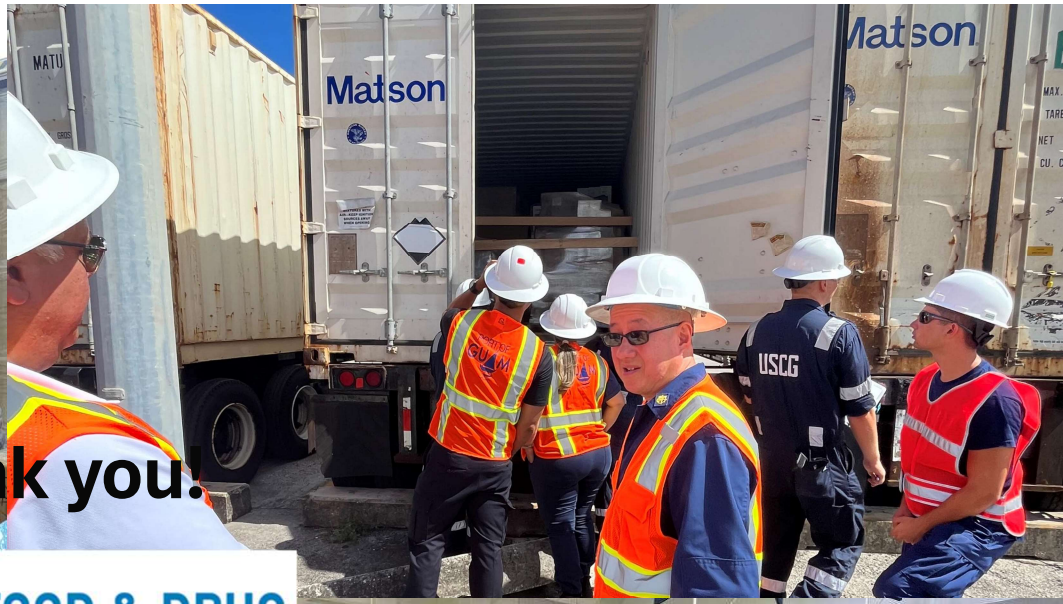
Progress

- Began collaborating with CBP and associated contractors in 2023
- Partnered on technical changes to support the November 2024 technical demonstration
- Collaborated with Mesur.io (contractor) on the food safety portion of the test to identify verifiable credentials of interest to FDA

Potential Benefits

- Expedited clearance with verifiable credential-based, pre-manifest data
- Transparent supply chains to reduce waste and spoilage
- Reduced paperwork/data entry, and preparation for future digital trade environments


FDA
Questions
www.fda.gov



Thank you!

FDA U.S. FOOD & DRUG ADMINISTRATION