

Association for Accessible Medicines GRx + Biosims Conference

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Agenda

- FDA's recent reorganization
- Role of FDA's inspections and investigations
- Well-trained inspectorate
- FDA's inspection database
- Strategic priorities for OII
- Questions



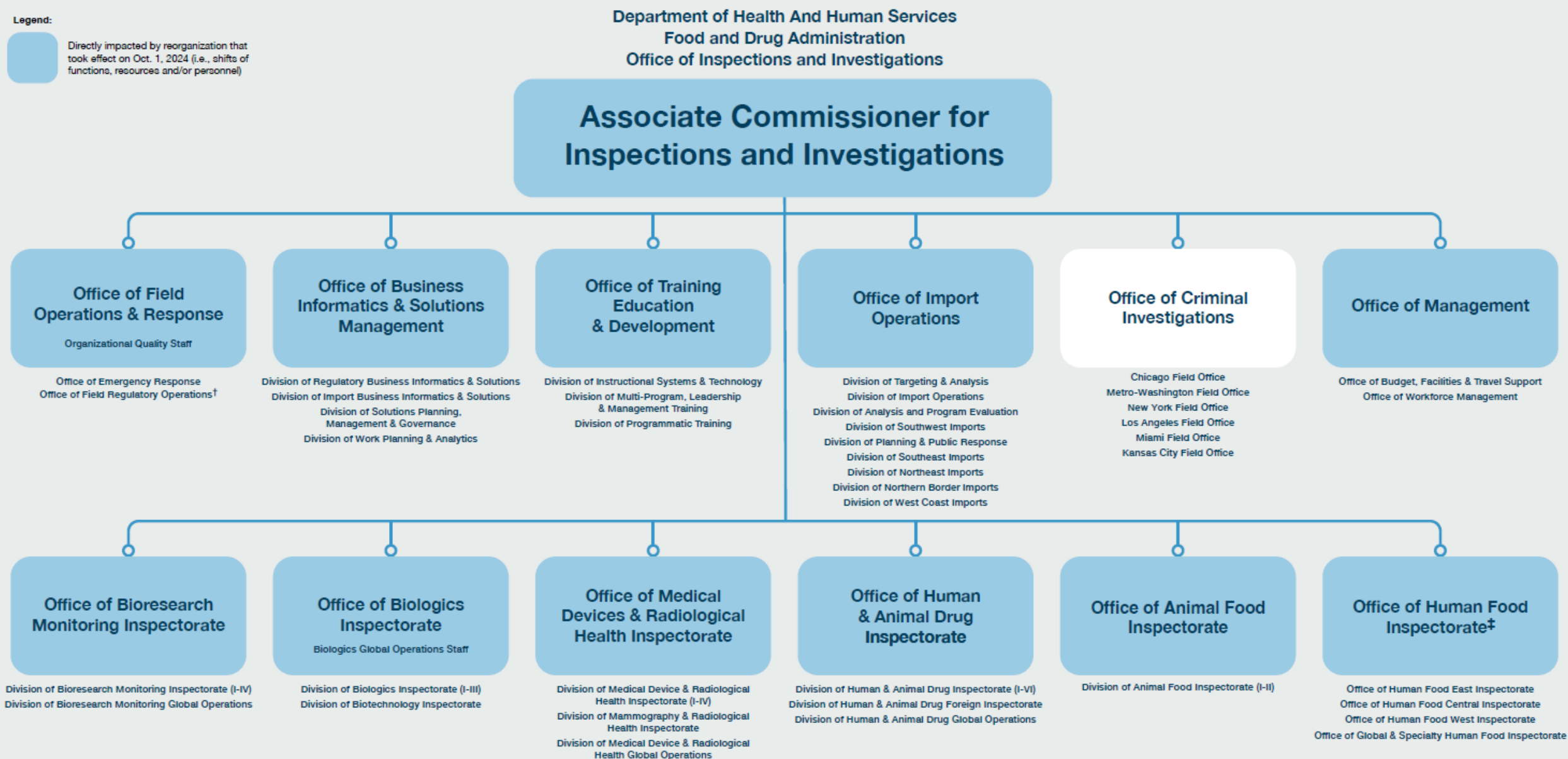
FDA Office of Inspections and Investigations (OII)

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

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)



†Includes Division of Tobacco Inspectorate

‡Includes specialized teams for products such as infant formula

The Role of Inspections and Investigations in Public Health

- Ensure firms meet regulatory standards
- Identify and address potential risks for consumers
- Ensure products meet safety and quality standards, instilling confidence in FDA-regulated products
- Educate regulated firms to maintain compliance





A Well-Trained Inspectorate Benefits Industry

- Clear expectations and guidelines enable compliance
- Through inspections, firms can identify potential issues early and take corrective actions, reducing costly recalls, regulatory actions, drug shortages or product delays
- Partnering with the FDA enables firms to proactively ensure products meet or exceed regulatory standards

Importance of Quality and Why it Matters

- . Quality is critical to the FDA's oversight
- . Directly impacts product safety and efficacy
- . Poor quality could result in products that harm consumers or fail to deliver intended benefits





Commitment to Protecting and Promoting Public Health

- Every day, FDA employees ensure the safety and efficacy of products via informed decisions based on science and data
- Public trust in the FDA is rooted in the expertise, commitment, and passion of our workforce

The FDA's Unique Approach: Scientific Rigor & Collaboration

- Our decisions are grounded in science, and diverse voices across disciplines ensure the best possible regulatory outcomes
- Collaboration with industry and transparent communication about regulatory standards and decisions ensure a strong partnership



FDA's Inspection Data Dashboard



[Data Dashboard Home](#) [Compliance Dashboards](#) > [FSMA Data Search](#) > [Resources](#) >

FDA Data Dashboard

Compliance Dashboards

[Inspections](#)

[Compliance Actions](#)

[Recalls](#)

[Imports Summary](#)

[Import Refusals](#)

[Imports Entry](#)

FSMA Data Search

Find firm compliance and enforcement information.

[Search Firm Information](#)

[LAAF Participants](#)

[TPP Participants](#)

[Approved VQIP Importers](#)

NEW!

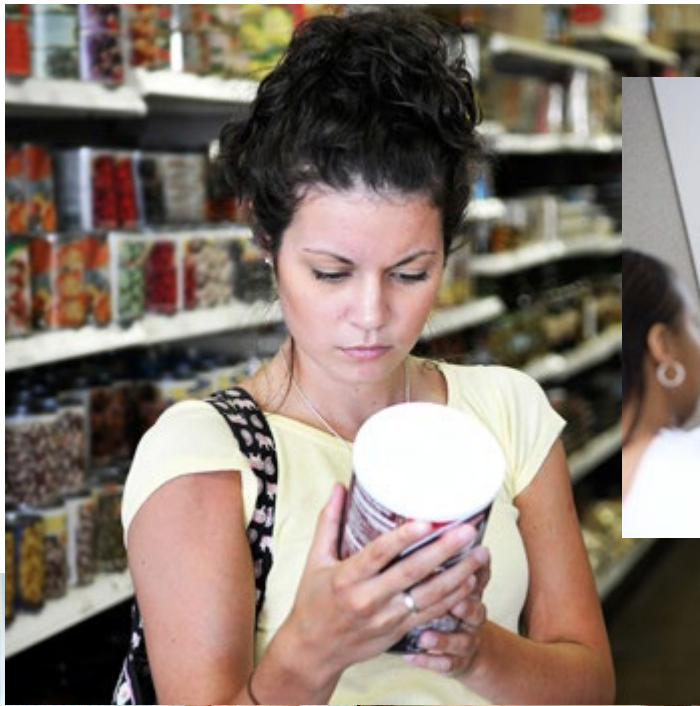
- Dashboard has been integrated with the [ORA Unified Logon](#) application. To obtain the credentials necessary to use the API, please submit authorization key requests using the online [ORA Unified Logon](#) application.
- Published 483s data is now available on the [Inspections Dashboard](#) and Firm Profiles.
- LAAF-accredited laboratory capacity and respective compliance dates have been added to the [LAAF Dashboard](#).



The FDA created the Data Dashboard to increase transparency and accountability by displaying and allowing the analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics.

OII Priorities

- Continue implementing the reorganization
- Investing in our workforce
- Modernize and update our procedures
- Broaden the narrative about regulatory coverage and inspectional outcomes
- Promote FDA's world class inspectorate



Questions?

