U.S. FOOD & DRUG ADMINISTRATION

Association for Accessible Medicines GRx+Biosims Conference

November 3, 2026

Elizabeth Miller, Pharm.D.

Associate Commissioner for Inspections and Investigations

OII's Mission & Vision

Mission

Our mission is to **conduct rigorous, transparent,** and **science-based inspections and investigations**, while providing real-time evidence and insights that are essential in empowering fact-based regulatory decisions **to protect public health**.

Vision

Our vision is that OII's global inspections and investigations ensure FDA-regulated products are **safe, trusted,** and **accessible**.

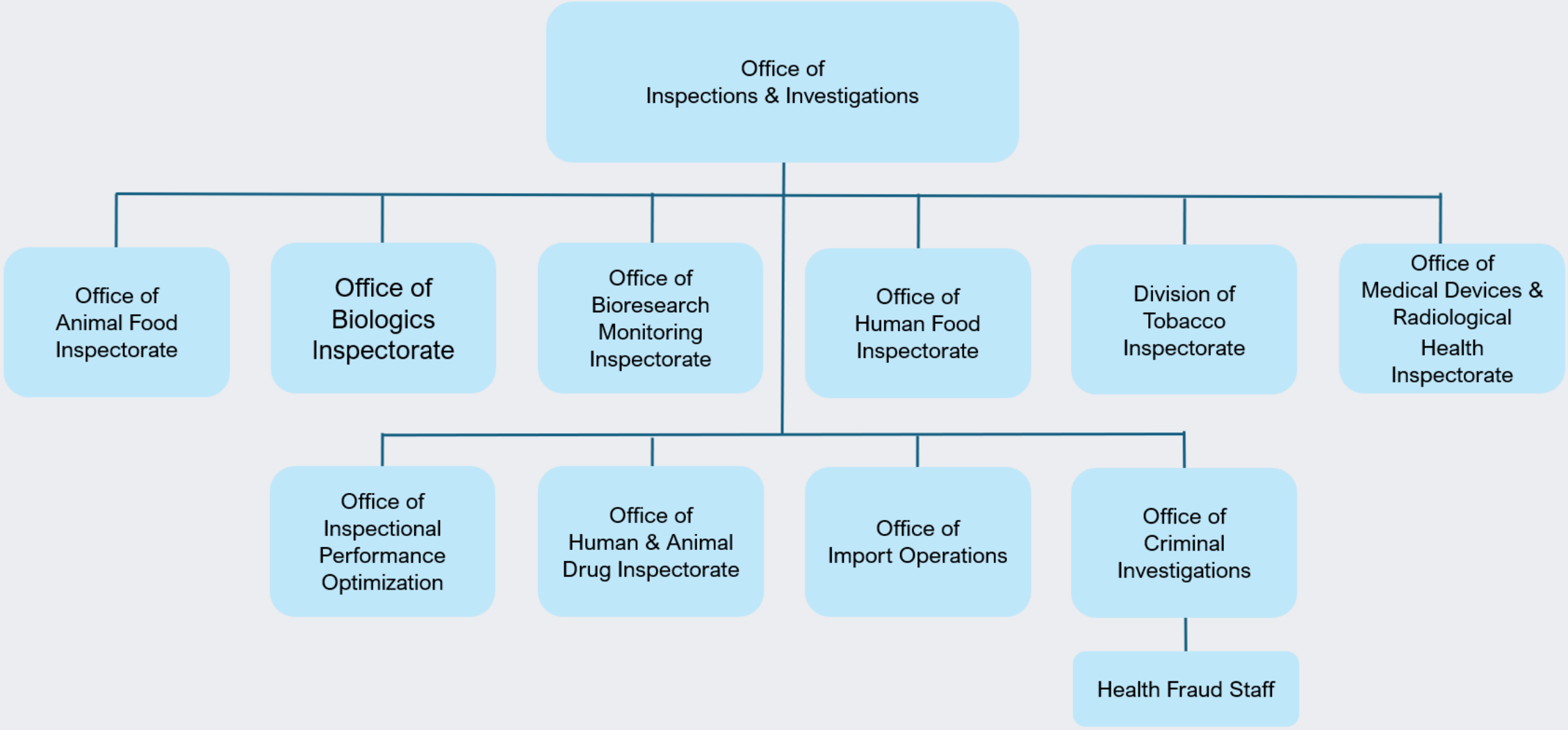
OII is at U.S. borders, in International Mail Facilities, and in more than 100 countries worldwide scrutinizing the products U.S patients and consumers rely on—ensuring their production, manufacturing, and importation comply with federal law.

Office of Inspections and Investigations





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



U.S. FOOD & DRUG ADMINISTRATION

What Changed in 2026

More targeted oversight — with the same expectation of continuous CGMP compliance

01

ONE-DAY ASSESSMENTS

Targeted inspectional assessments designed to address defined risks efficiently.

02

UNANNOUNCED FOREIGN INSPECTIONS

A larger unannounced footprint to strengthen parity across the global supply chain.

03

PRECHECK

Earlier engagement with new manufacturing facilities to identify readiness issues sooner.

04

RISK-INFORMED TOOLS

Records review, remote interactions, and data help focus on the areas of greatest risk.

The objective is not simply more inspection activity. It is better information, at the right time, focused on risk.

U.S. FOOD & DRUG ADMINISTRATION

Quality, Access & Supply Resilience

For generics and biosimilars, these goals are mutually reinforcing.



Inspectional rigor and access are not competing objectives. A resilient supply chain depends on quality that is built in — and sustained every day.

FDA's role is to apply oversight consistently, proportionately and based on risk.

FDA's Public Health Pillars



Strategic Priorities



Strengthening the Workforce



Optimizing Inspections



Modernizing Work Planning



Nurturing Collaborations



Enhancing OII Culture

U.S. FOOD & DRUG ADMINISTRATION

What We Ask of Industry

Three practices make oversight more effective — and strengthen confidence across the system.

1

CONTINUOUS READINESS

Operate every day as though an inspection could occur. CGMP compliance is a continuous obligation, not an event.

2

TRUSTWORTHY DATA & TRANSPARENCY

Maintain reliable records and surface problems early. FDA decisions are only as strong as the evidence available to us.

3

CANDID FEEDBACK

Tell us what is working, where implementation is creating friction, and where greater clarity would improve execution.

Our responsibility is to be rigorous and consistent — and to keep learning how to do the work better.



U.S. FOOD & DRUG
ADMINISTRATION