Office of Inspections and Investigations

We are the frontlines.

FDA's Office of Inspections and Investigations (OII) keeps America's food and medical supplies safe and effective.

We **inspect** the full range of FDA-regulated products at home and abroad, including foods, human and animal drugs, cosmetics, and medical devices. We also **investigate** complaints, **screen** imports, **collaborate** with domestic and foreign partners, and **respond** to emergencies to protect America's public health.

33 Minutes

Every 33 minutes, we initiate an inspection or a regulatory activity.

~1 Billion

In FY22, we helped remove nearly one billion potentially unsafe items from the market.

50 Million

OII makes more than 50 million import admissibility decisions every year.

$25 Billion

The Office of Criminal Investigations has recovered $25 billion from its investigations in the past 30 years.

196+
Offices

50
States + 5 Territories

93
Countries

As FDA's global frontline, OII is a world-class, trusted, and valued partner who identifies, collects, and evaluates evidence to empower integrated regulatory decision-making, which builds stakeholder trust and protects public health.

Inspect

We inspect food, drugs, medical devices, cosmetics, biologics, and tobacco products in the United States and around the world, enforcing FDA regulations that protect the American public.

- In collaboration with our regulatory partners, OII conducts **30,000 inspections** per year, both domestically and internationally.
- Every year, OII employees fly over **26 million miles** to conduct FDA operations in the U.S. and abroad.
- If violative conditions are found during an inspection, **we take action,** including working with the firm to conduct a recall or requiring the manufacturer to correct the problem.
- OII also conducts inspections to ensure that data submitted for approval of a new medical product is accurate, reliable, and that participants in clinical and non-clinical studies are protected. During COVID-19, our investigational operations enabled decisions for **16 vaccine applications and seven therapeutics applications.**
- OII investigators generate more than **240,000 documents a year** during their inspections, all of which are stored for immediate use and sharing inside and outside the agency.

Investigate

We conduct investigations to determine and document facts concerning a particular issue so the FDA can make informed and sound decisions.

- Every year, we conduct **~10,000 investigations,** covering consumer complaints, health fraud, product tampering, and disaster investigations.
- **Investigations can be performed at almost any location.** For instance, OII can conduct an investigation at a retail establishment to ensure recalled products have been removed from the market or at a consumer's residence to collect product samples of concern.
- OII is the **only federal public health agency with a criminal investigatory enforcement arm:** the Office of Criminal Investigations. This office investigates illegal U.S. imports, consumer product tampering, and counterfeit drugs—and makes arrests.
- Domestically, OII maintains an inventory of over **190,000 establishments** that are prioritized for oversight based on regulatory requirements and risk.

Screen

To protect consumers from products that appear to be violative from entering the domestic market, we screen imports at U.S. points of entry, including ports, airports, and border crossings.

- OII staff are assigned to **eight U.S. Postal Service international mail facilities** to examine imported goods entering the country.
- Every year, we screen and review **100% of FDA-related products of foreign origin** entering the domestic market.
- Annually, OII prevents **650 million medical products** that appear to be violative and **256 million pounds of food** that appear to be violative from entering the market from international sources.

Collaborate

We collaborate with our counterparts at the federal, state, local, tribal, territorial, and international level to enhance the FDA's response to global public health emergencies.

- OII works alongside **a wide range of international, federal, and state agencies** such as U.S. Customs and Border Protection, the North Dakota Department of Health, and the European Medicines Agency.
- We also work closely with **influential regulatory associations,** including the Association of Food and Drug Officials, the Association of American Feed Control Officials, and the National Environmental Health Association.
- We collaborate with our state, local, territorial, and tribal partners to conduct on average **14,000 inspections a year** within the United States.
- OII has established **dozens of mutual recognition agreements** with foreign countries for human and animal pharmaceutical inspections, avoiding the need for duplicative inspections and enabling regulators to maximize inspection resources.
- We train an average of **16,000 people per year,** providing over **250,000 hours of training** to OII employees and state, local, tribal and territorial regulatory partners.

Respond

We are the FDA's lead office for responding to emergencies across the country, including natural disasters, pandemics, and foodborne outbreaks.

- OII has a network of **25 cross-programmatic emergency response coordinators** who manage incidents including contaminated over-the-counter medicines, contaminated animal food, and threats to the supply chain.
- After a global natural disaster, such as a typhoon or hurricane, OII **assesses affected companies' ability** to safely manufacture food, drugs, and medical products.
- Depending on the scope of the emergency, OII **activates an incident management team** to coordinate effectively across FDA and with public health stakeholders.
- We work alongside our state, local, and federal partners to **protect public health and food safety during high-profile events** such as the presidential inauguration or Olympics.