

## Office of Inspections and Investigations

# We are the frontlines.



FDA's Office of Inspections and Investigations (OI) 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.

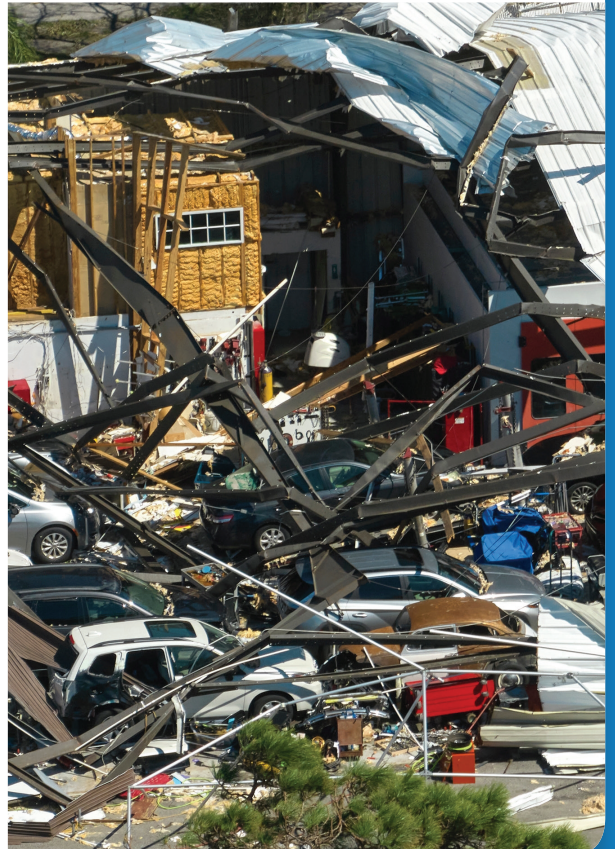




# Respond

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.



**FDA**