Office of Regulatory Affairs

We are the frontlines.

As the lead for FDA inspections and investigations, the Office of Regulatory Affairs (ORA) 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

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

$25 Billion

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

270+ Offices

50 States + 2 Territories

15 Scientific Laboratories

93 Countries

As FDA's global frontline, ORA 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, ORA conducts **30,000 inspections** per year, both domestically and internationally.
- Every year, ORA 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.
- ORA 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.**
- ORA 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, ORA 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.
- ORA 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, ORA 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.

- ORA 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, ORA 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

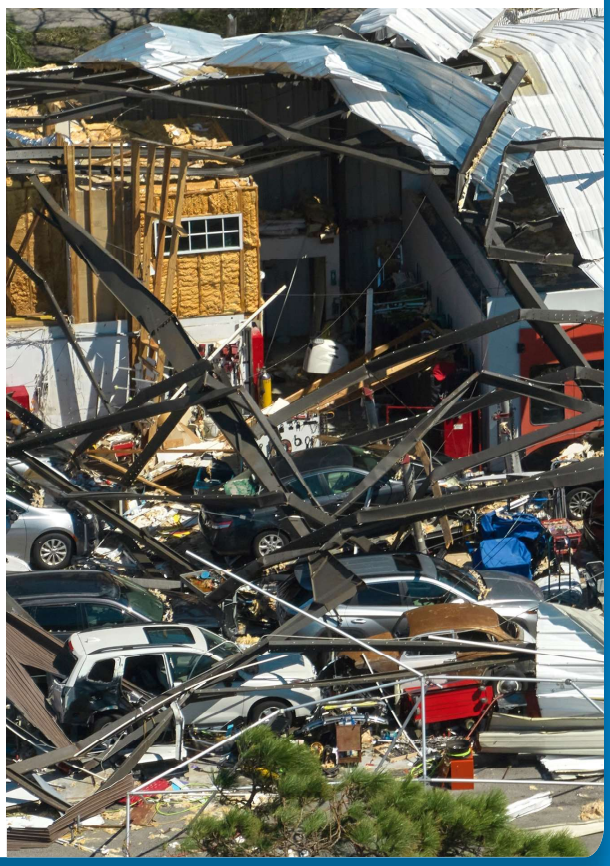
We collaborate with our counterparts at the federal, state, local, tribal, territorial, and international level to enhance the FDA's response to global public health emergencies.

- ORA 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.
- ORA 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 ORA employees and state, local, tribal and territorial regulatory partners.

Respond

We respond to emergencies across the country, including natural disasters, pandemics, and foodborne outbreaks.

- ORA 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, ORA **assesses affected companies' ability** to safely manufacture food, drugs, and medical products.
- Depending on the scope of the emergency, ORA **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.



Analyze

We provide quality analytical results through a world-class regulatory lab network, enabling timely determination of the compliance and non-compliance of FDA-regulated products.

- On a yearly basis, ORA labs analyze over **33,000 human and animal food samples,** from apples to alfalfa; **4,000 drug samples,** including chemotherapeutics and insulin; and **300 medical devices,** such as mammography machines and surgical equipment.
- ORA laboratories **develop and validate regulatory methods,** covering everything from radionuclides in food to the decomposition and sensory analysis of seafood to counterfeit and adulterated drugs.
- **All 15 ORA laboratories are accredited to ISO-17025,** belong to a national quality network, and have expansive proficiency testing and audit programs.
- The ORA laboratory network works with **the System Recognition Program, the European Food Safety Agency, Health Canada, the Australian Food Safety System, the Pharmaceutical Inspection Convention Scheme, and private labs.**
- **The Food Emergency Response Network partners with 168 federal, state, and local labs** across the U.S. with capabilities to assist with response to sudden food safety or food defense events.