

# Safeguarding Product Entry into the U.S.



## Who We Are

Composed of roughly 775 staff, OIO is FDA's lead team for all field import operations, including conducting field investigations and compliance activities in over 300 ports of entry and import facilities across the U.S. and abroad.



Office of Inspections and Investigations

## Our Mission

Protect consumers and enhance public health by ensuring access to safe, effective, and quality FDA-regulated products of foreign origin.

## Our Public Impact

- Annually prevent entry of 650 million medical products that appear to be violative and 256 million pounds of food that appear to be violative.
- In a typical year, examine more than 41,000 packages entering the U.S. via an international mail facility, preventing entry of roughly 60,000 unapproved drug products.
- Screen and review FDA-related products being offered for import in the United States. This equates to an import related decision every 2.5 seconds.
- Ensure all products regulated by FDA must meet the same requirements, whether imported from abroad or produced domestically.

## Our Frontline Activities

- Investigate, review, obtain test samples, and determine real-time admissibility on FDA-regulated products offered for entry into the U.S. coming through ports of coverage.
- Conduct inspections and investigations of importers and related facilities.
- Conduct analyses and targeting assessments based on potential threats, feedback, recalls, and other information.
- Coordinate import operations with the U.S. Customs and Border Protection (CBP), and other federal and foreign agencies.
- Improve operational efficiency and refine targeting using cutting edge technology
- Safeguard the U.S. food supply against bio-terrorism and ensure supply chain stability.

