U.S. FOOD & DRUG ADMINISTRATION


# 2024 ANNUAL REPORT

Office of Inspections and Investigations

Ombudsman Program

# OII OMBUDSMAN MESSAGE

The Office of Inspections and Investigations (OII) Ombudsman Program (OOP) remained a vital resource in 2024, assisting external stakeholders in addressing challenges and gaining clarity in navigating complex regulatory matters overseen by OII. With 334 inquiries received—a 5% rise from the previous year—the program addressed a broad spectrum of concerns. Topics addressed included inspection-related inquiries, import concerns, recall processes, and general regulatory support, reflecting sustained engagement and trust in the OII Ombudsman's role.

Of the total inquiries received, 88% were resolved informally, helping stakeholders avoid unnecessary escalation to formal processes under 21 CFR 10.75. This resolution rate highlights the program's continued commitment to efficient and timely issue resolution.

The OII Ombudsman also facilitated 38 stakeholder meetings or facilitated discussions and participated in 13 outreach activities, including presentations, trainings, and virtual engagement events. These efforts expanded awareness of the program's role and strengthened communication between stakeholders and the agency.

Additionally, the OOP identified four recurring issues, which were shared with leadership and contributed to procedural updates, clarification in verbal guidance, and improved inspection communications, reinforcing OII's commitment to continuous improvement and transparency in alignment with 21 CFR 10.115.

Looking ahead, the OOP aims to build on this progress by continuing to enhance data collection and analysis, expanding outreach to additional stakeholder groups, and supporting broader FDA efforts to foster regulatory efficiency and responsiveness. OOP remains dedicated to promoting trust, fairness, and efficiency in all agency interactions.

## Contact Info

Call:

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Learn More:

www.FDA.gov/OIIOmbudsman

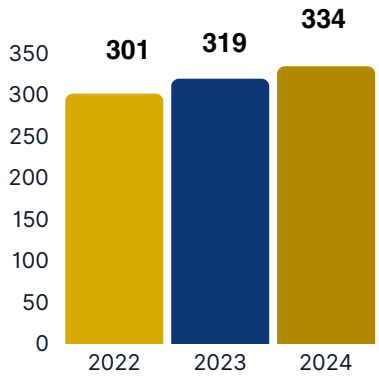
Mail:

US Food & Drug Administration
OII Ombudsman
555 Winderely Place #200
Maitland, FL 32751

*You can contact the OII Ombudsman anonymously via mail.

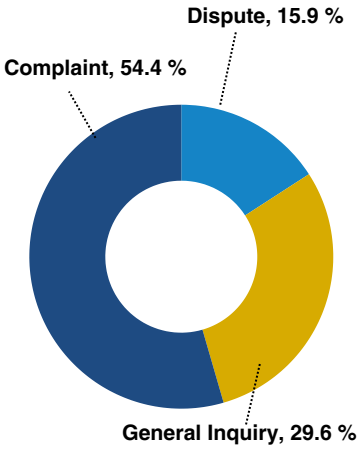
# 2024 QUICK FACTS

## Number of Inquiries



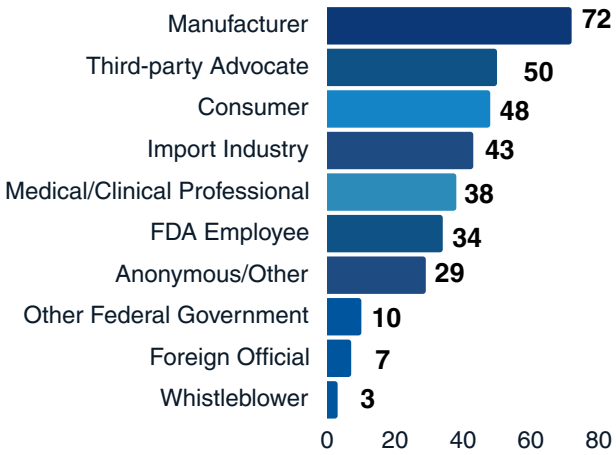

An inquiry is a substantive interaction between the OII Ombudsman and an internal or external stakeholder seeking information or assistance.

## Inquiry Summary



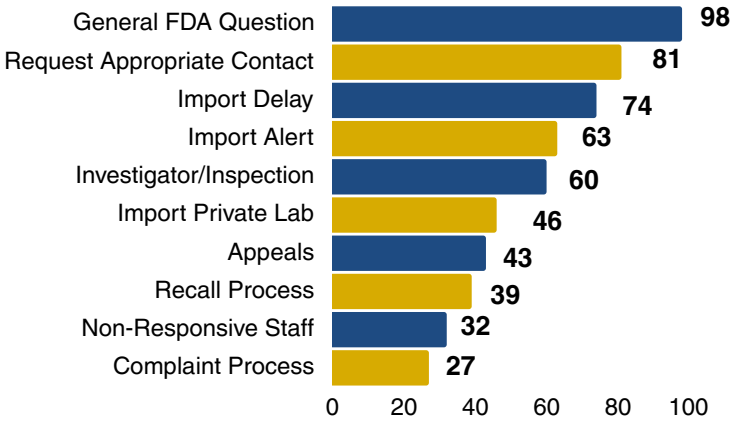

The OOP summarizes the inquiry concerns into three primary categories: Dispute, Complaint, and General Inquiry.

## Stakeholder Categories



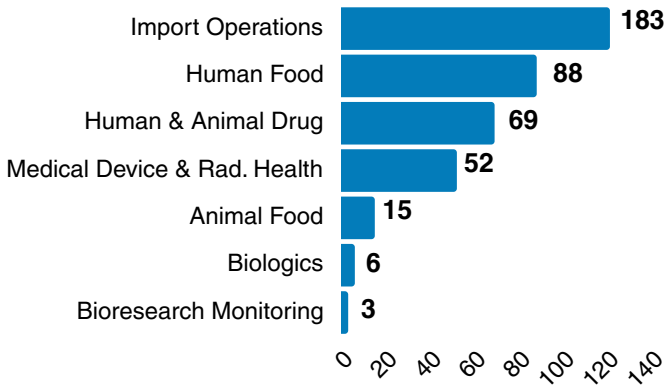

A stakeholder is any interested party requesting assistance with a dispute, concern, or confidential matter related to OII processes. Stakeholder categories are based on voluntary self-identification.

## Inquiries by Reported Concern




The ten most frequently reported concerns are summarized on this chart. In 2024, 334 stakeholders reported a total of 563 concerns.

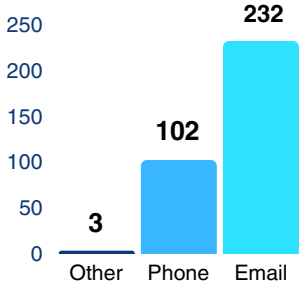
## Inquiries by OII Program




Approximately 74% of the concerns received were directly related to an active OII regulatory process. The remaining 26% involved non-operational experiences or issues, not specifically tied to a current OII process.

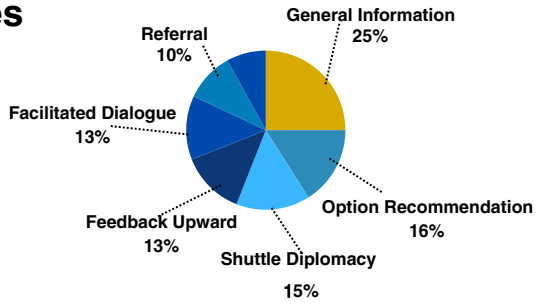
## How Stakeholder Contact the OOP

The three inquiries received as other involved complaints where the complainant wanted to remain anonymous and were received via postal mail or fax.



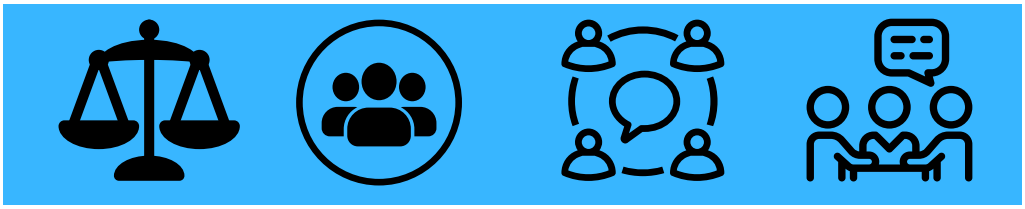

## Closure Categories

Closure of an inquiry occurs when a solution is determined, the inquirer no longer requests assistance, or all viable options are exhausted as determined by the ombudsman.



# OOP MISSION AND SCOPE

The OOP fosters effective communication and collaborative problem-solving by offering a confidential, impartial space to explore concerns and identify potential solutions. Throughout the year, the OII Ombudsman supported informal dialogue and issue clarification efforts across various regulatory matters, including inspection activities, import processes, and post-market actions. While the OII Ombudsman does not engage in legal determinations, formal processes, or matters in litigation, the program plays a vital role in complementing existing agency channels by serving as an informal pathway for resolution—especially when traditional routes are exhausted or stalled. The OII Ombudsman analyzes and learns about all perspectives of an issue by:



**Reviewing the applicable laws, regulations, policy, and data**

**Talking with individuals and/or stakeholders involved**

**Meeting with OII or other FDA officials**

**Facilitating internal and external discussions**

In 2024, the OOP enhanced outreach through virtual presentations and stakeholder engagements while internally supporting OII employees through educational briefings on effective communication and conflict-sensitive approaches. The OII Ombudsman also continued monitoring recurring concerns to identify themes that have informed procedural improvements and supported the OII's commitment to continuous improvement and regulatory efficiency.

Notably, the services provided by the OOP remain voluntary and are not intended to delay OII timelines or substitute for formal agency procedures. The OII Ombudsman neither accepts legal notice nor makes final decisions on behalf of OII or FDA. However, the program continues to serve as a trusted and accessible resource for promoting fair processes and constructive dialogue, even in challenging or complex circumstances.

# OOP RECOMMENDATIONS

## Stakeholder Education and Engagement

**Background**:
External stakeholders frequently report difficulty accessing clear, centralized information about regulatory expectations and navigating critical OII processes such as inspections, import alerts, investigations, and sample collections. These challenges can result in confusion, preventable delays, and unintended noncompliance. Additionally, stakeholders stated they have limited structured opportunities to engage with OII management or ask clarifying questions outside formal interactions.

**Recommendation**:
To address these concerns, OOP recommends that OII explore developing a Stakeholder Education Hub. The hub could be launched as a dedicated webpage that brings together existing educational resources, organized around common concerns in a clear, question-and-answer format. A dedicated website could also serve as a single, accessible entry point for stakeholders seeking clear, process-specific guidance, timelines, and expectations.

**Proposed Features**:

- A curated list of FAQs addressing commonly reported concerns, such as what to expect during inspections, how to respond to a Form FDA 483, and where to find updates on regulatory changes
- Visual tools such as decision trees, flowcharts, and timelines to simplify complex processes
- Integration with existing resources and links to relevant guidance documents
- A framework that can grow to include feedback-informed webinars and recorded Q&A sessions

**Impact**:
This recommendation could improve transparency, reduce miscommunication, and support stakeholder confidence in regulatory engagement. It also offers a proactive strategy for education and engagement, helping prevent issues before they escalate into formal disputes.

# Program Years 2017 - 2024

**2358**

**Stakeholders Assisted**

**3172**

**Concerns Facilitated**

*From 2017 to 2024, the OOP assisted 2,358 stakeholders and addressed 3,172 individual concerns, reflecting its sustained role in empowering fact-based regulatory decisions to protect public health.

## For assistance or more information:

FDA.gov/OIIOmbudsman

844-871-4536

OIIOmbudsman@fda.hhs.gov