FDA U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF REGULATORY AFFAIRS

2023 ANNUAL REPORT

ORA Ombudsman Program

Ombudsman Message

Erica M. Katherine, ORA Ombudsman

I am pleased to present the ORA Ombudsman Program (OOP) annual report for the calendar year 2023 (CY23). This report provides a comprehensive overview of the program's activities, including data collection, trends analysis, observations, and recommendations based on the feedback received from stakeholders throughout the year.

As the Ombudsman of the ORA program, I serve as a neutral and confidential resource for all stakeholders, including FDA staff, regulated industry, other government entities, and the public. The OOP process involves four key steps: intake, engagement, facilitation, and feedback. I actively listen to stakeholders, engage with the process holders to identify solutions, facilitate discussions between parties, and provide feedback and recommendations for resolution. These actions fulfill the program's mission by enhancing the operations of ORA, improving communication channels, resolving disputes, and fostering positive relationships with stakeholders.

Throughout this report, you will find detailed insights into the types of issues addressed by the program, the process followed to resolve them, and the essential findings and recommendations based on the data collected. This report will provide valuable information and demonstrate our commitment to transparency, accountability, and stakeholder engagement.

Highlights from CY23 include:

- The OOP supported and facilitated the resolution of 509 concerns raised by 319 stakeholders.
- Through training and virtual outreach initiatives, an additional 488 internal and external stakeholders received information about the ORA and OOP.
- Released the CY 22 OOP Annual Report that reached via social media over 42,000 stakeholders across two LinkedIn posts, with an average engagement rate of 13%. These statistics indicate strong stakeholder interest and engagement with the report's content and highlight the value of the Ombudsman Program's communications strategy.

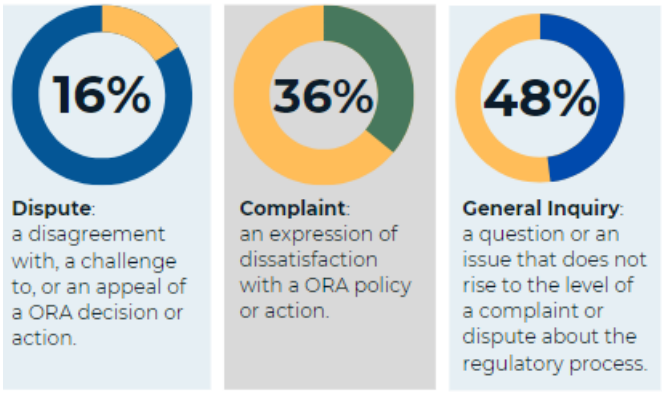
The OOP is an informal independent, neutral, and confidential resource for dispute resolution.

I encourage you to review this report carefully and provide any feedback or suggestions you may have. Your input is crucial in helping us improve our services and better meet the needs of our stakeholders.

2023 Quick Facts

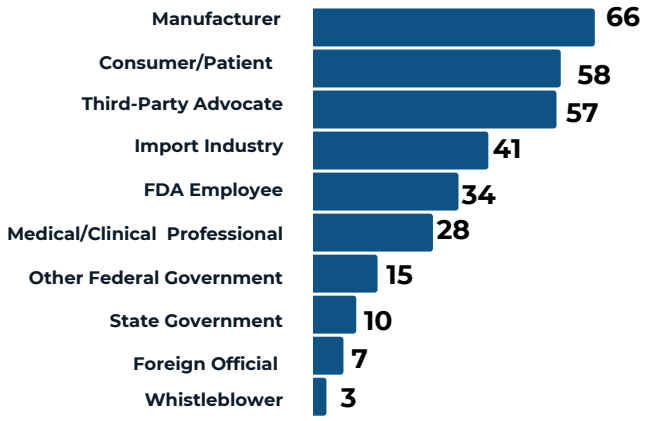
319 Number of Inquiries Received by OOP

An inquiry can be defined as any interaction between the ORA Ombudsman and an external or internal stakeholder. The OOP categorizes the inquiry concerns it addresses into three primary categories:



21% of stakeholders seeking assistance are manufacturers.

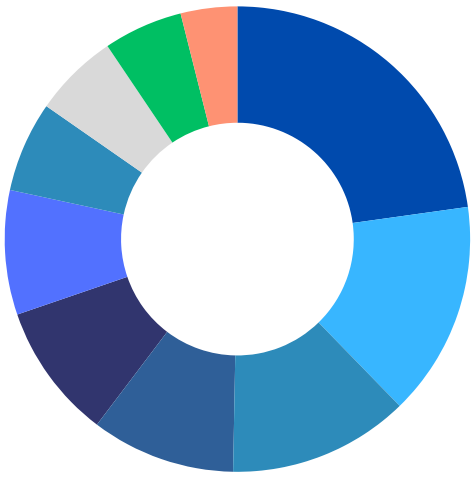
The ten most frequent stakeholder categories engaging the OOP service are:



509 Number of Reported Concerns

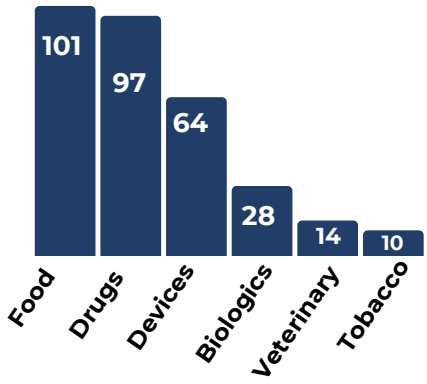
In 2023 stakeholders reported a total of 509 concerns. The ten most frequent inquiry concerns raised are:

General FDA Question	116
Request Appropriate Contact	76
Import Delay	64
Investigator/Inspection	51
Appeals	48
Recall Questions	44
Import Alerts	32
Complaint Process	30
Non-Responsive Staff	28
Non-FDA Concern	20



53% of OOP inquiries are complaints or general inquiries related to medical products.

Inquiries by FDA Regulated Product

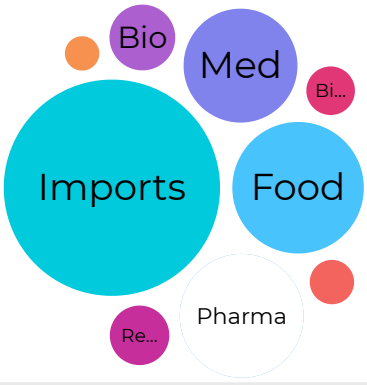


31%

of inquiries related to import operations are categorized as general inquiries.

Inquiries by ORA Program/Office

Import Operations	119
Human and Animal Food Operations	44
Pharmaceutical Quality Operations	39
Medical Device and Radiological Health Operations	33
Biological Products Operations	11
Regulatory Science	9
Biological Monitoring Operations	6
Tobacco Operations	5
Communication and Project Management	3



Program Summary

The OOP Ombudsman abides by ethical principles and standards established by the Coalition of Federal Ombudsman, the U.S. Ombudsman Association, and the International Ombudsman Association. Adherence to core standards allows the ombudsman to advocate for fair processes and assist ORA's external and internal stakeholders.

Effective communication is a cornerstone of the OOP's approach. The program promotes understanding and collaboration between ORA employees and stakeholders through targeted external outreach and internal educational initiatives.

It's important to note that the OOP complements the existing mechanisms in place for addressing stakeholder concerns. The OOP Ombudsman works alongside these channels, providing an additional avenue when other routes have been exhausted.

The program's commitment is facilitating constructive dialogue, reviewing relevant information, and finding creative solutions that benefit all parties involved. The ombudsman does not:

- Address matters in litigation or provide legal advice;
- Delay statutory, regulatory, or other ORA deadlines;
- Make decisions or legal determinations for the ORA;
- Serve as a formal office of legal notice for the ORA; or,
- Address internal workforce issues.

Core Standards

INDEPENDENCE

To ensure independence and objectivity the ombudsman does not report to any of ORA's enforcement program offices.

INFORMALITY

The services offered by OOP are voluntary and are not provided to initial any formal proceeding against ORA or FDA.

NEUTRALITY

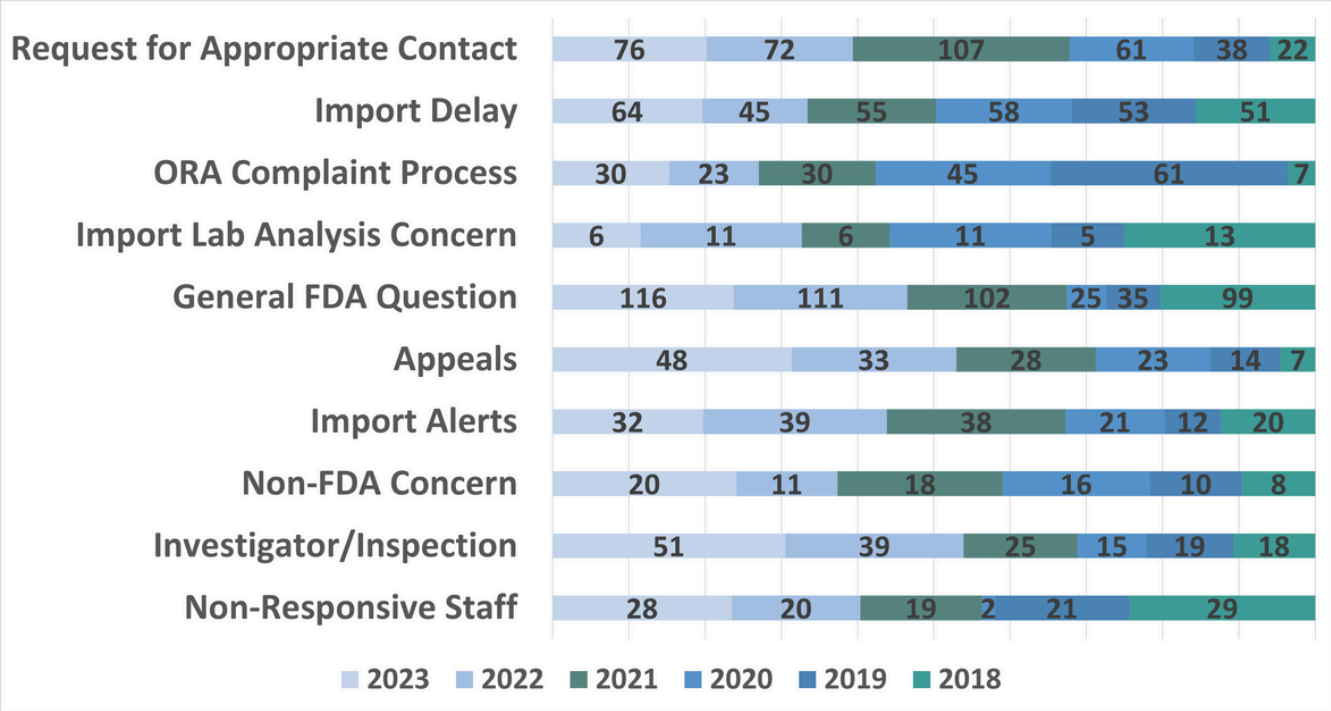
The ombudsman maintains a neutral position and does not represent or act as an advocate for any person or entity in a dispute. or act as an advocate for any person or entity in a dispute.

CONFIDENTIALITY

The Ombudsman takes all reasonable steps to safeguard confidentiality and does not share the identities of stakeholders who contact OOP.

Inquiries By Calendar Year

Communication with the ombudsman comprises a small percentage of data from self-selecting (contact with an ombudsman is voluntary) internal and external stakeholders and does not independently indicate systematic findings. While short-term data is valuable for identifying and proposing immediate actions, long-term data is crucial for comprehensively understanding and addressing systemic issues. Because both perspectives are essential, comparing the ten most frequently raised concerns across the past six calendar years (CY18 – CY24) can be used to gain insight into areas where there may be an opportunity to propose lasting, meaningful change.



Recommendations

The unique role of the ombudsman within ORA allows connections across management groups and program areas that strengthen the communication between external and internal stakeholders while maintaining the confidentiality of the individuals. Based on a review of the inquiries received in CY23, OOP offers the following recommendations for potential process improvements to address stakeholders' concerns.

Inspection Process: Stakeholders have reported challenges with communication during and after inspections, particularly regarding reporting differences of opinion and submitting large attachments or files. The following recommendations are proposed to address these communication challenges:

- Clear Guidance: Provide clear and concise guidance on how stakeholders can submit large attachments or files during or after an inspection, explaining the process and requirements. Stakeholders have noted that while some programs provide written instructions, others offer verbal instructions during closeout. Stakeholders would appreciate having these instructions available online at FDA.gov.

- Reporting Channels: Stakeholders can contact the OOP whenever they have concerns to share. However, for issues where confidentiality is not requested, stakeholders should first try to resolve the matter with program management. It is essential to clearly define the appropriate channels for stakeholders to report differences of opinion, starting with the inspector's supervisor and escalating to a division director if necessary.

Recall Process: Stakeholders have highlighted concerns regarding the termination of recalls, with inquiries about expected correspondence or communication from the FDA while the closeout is pending. This issue has become among the top ten reported to OOP in 2022 and 2023. Stakeholders are also seeking clarity on the timeframe for the termination process. The following recommendations are suggested to address these challenges:

- Communication Matrix: Develop a communication matrix outlining the recall process and any potential discretionary measures the Agency may consider during the closeout review period.

- Resource Review: Review current resources available online at FDA.gov to ensure the most current information is provided for recall termination within all regulatory programs. This review will also help stakeholders submit all necessary information for closeout during the initial request for termination and decrease the need for several resubmissions.

The preceding recommendations are intended to enhance communication transparency and efficiency, thereby improving stakeholder experience and optimizing agency processes.

Outlook for 2024

In 2020, OOP established the following overarching goals to guide the program's activities:

- Capture and communicate individual and systematic process issues to leadership and support resolutions for reported concerns by advocating for fair process solutions.
- Expand education about OOP and further ongoing engagement with stakeholders through internal and external outreach initiatives.
- Optimize ways to receive inquiry feedback and provide perspectives from internal and external stakeholders.
- Demonstrate leadership in ombudsman practice and profession by maintaining expert-level ombudsman skills and expanding knowledge base.

OOP will continue to accomplish milestones toward these overarching goals and develop new milestones to be implemented in 2024 and 2025. The 2024 OOP Annual Report will celebrate the 10th year of the program and include updates on all milestones and goals.

ORA Ombudsman Program (OOP)

Program Years 2017 - 2023

2024

Number of Stakeholders Assisted

2609

Number of Concerns Closed

For assistance or more information:

FDA.gov/ORAOmbudsman

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