2022

ANNUAL REPORT

ORA Ombudsman Program

FDA U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF REGULATORY AFFAIRS

OMBUDSMAN MESSAGE

Erica Katherine, ORA Ombudsman

Navigating a Path to Resolution

The Office of Regulatory Affairs (ORA) Ombudsman Program (OOP) of the U.S. Food and Drug Administration (FDA) serves as a neutral, confidential resource to improve communication channels, resolve disputes, and foster positive relationships with ORA stakeholders. The OOP Annual Report summarizes the major functions and activities of the ombudsman in calendar year 2022 (CY22).

In CY22, the OOP supported and facilitated the resolution of 425 concerns raised by stakeholders in a total of 301 inquiries. The OOP also provided information on the existing communication channels in ORA that are available to resolve concerns, and through in-person and virtual outreach initiatives, how and when to contact the OOP.

Every year, the OOP develops milestones for achieving its goals. Please refer to page 9 for a list of the overarching goals and future milestones. In CY22, the OOP achieved the following milestones:

- Developed and launched a customer satisfaction survey to obtain feedback about the efficiency and effectiveness of the OOP
- Closed 90% of inquiries in accordance with the closure parameters for the OOP
- Featured as a guest speaker for the ORA Speaks podcast, as part of the internal outreach efforts for Ombuds Day 2022
- Directed the development of a communications plan and key messaging for the OOP to increase awareness with external stakeholders and provide consistent communication to all stakeholders

OOP advocates for fairness of process for all ORA stakeholders. Please contact the OOP Ombudsman if you need assistance or have feedback about this report.

Contact Info

Call:

(844)-871-4536

Email:

ORAOmbudsman@fda.hhs.gov

Submit Feedback:

Take Survey

Learn More:

www.FDA.gov/ORAOmbudsman

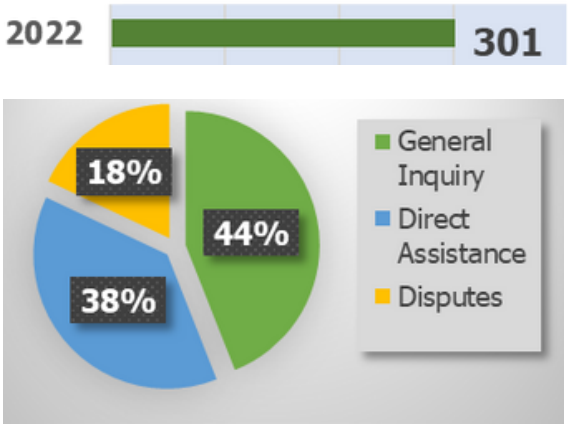
Mail:

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

You can contact the ombudsman anonymously via mail.

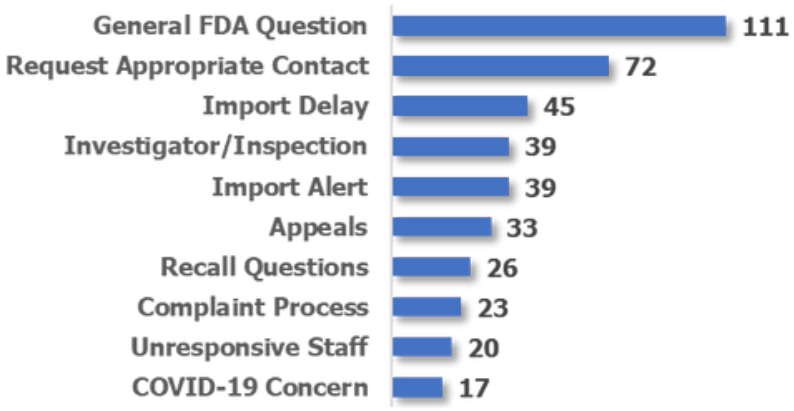
QUICK FACTS

INQUIRY TOTAL AND OUTCOMES



Inquiries requiring direct assistance or that involve dispute issues were 56% of total inquiries. To recommend solutions for these complex inquiry types, the ombudsman may need to initiate multiple communication points in ORA and FDA.

MOST FREQUENT INQUIRY CONCERNS



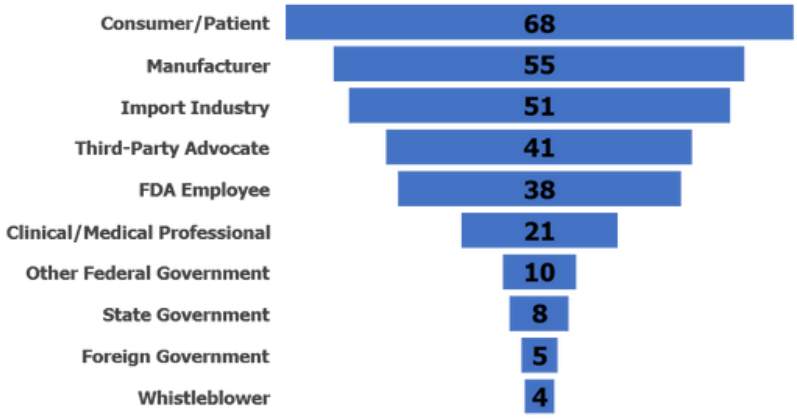
In 2022 stakeholders raised a total of 425 concerns. Approximately 62% of these concerns were directly related to or involved a specific ORA program area.

HOW STAKEHOLDERS CONTACT THE OOP

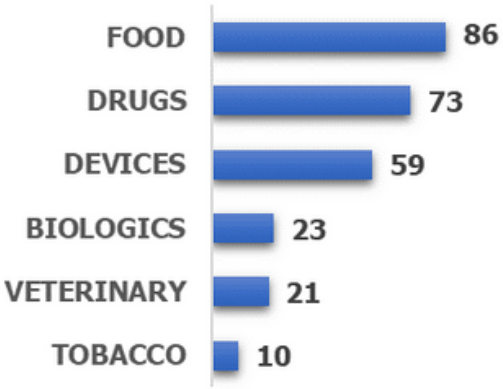
EMAIL	PHONE	MAIL
267	32	2

The two inquiries received via mail involved whistleblower complaints where the complainant wanted to remain anonymous.

STAKEHOLDERS USING THE OOP SERVICE



INQUIRIES BY FDA REGULATED PRODUCT



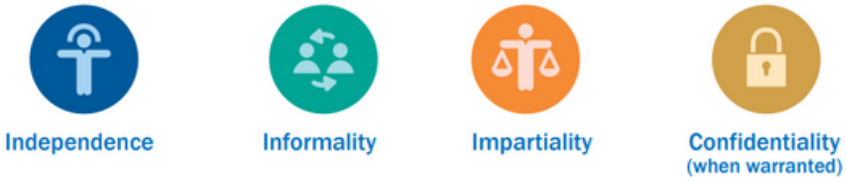
Twenty percent of food related inquiries were small business firms requesting information about food labeling exemptions or help with understanding food regulations.

INQUIRIES BY PROGRAM/OFFICE

Import Operations is the most public facing program/office within ORA, and in 2022, the program reviewed a total of 51.2 million entry lines of product intended for domestic distribution.

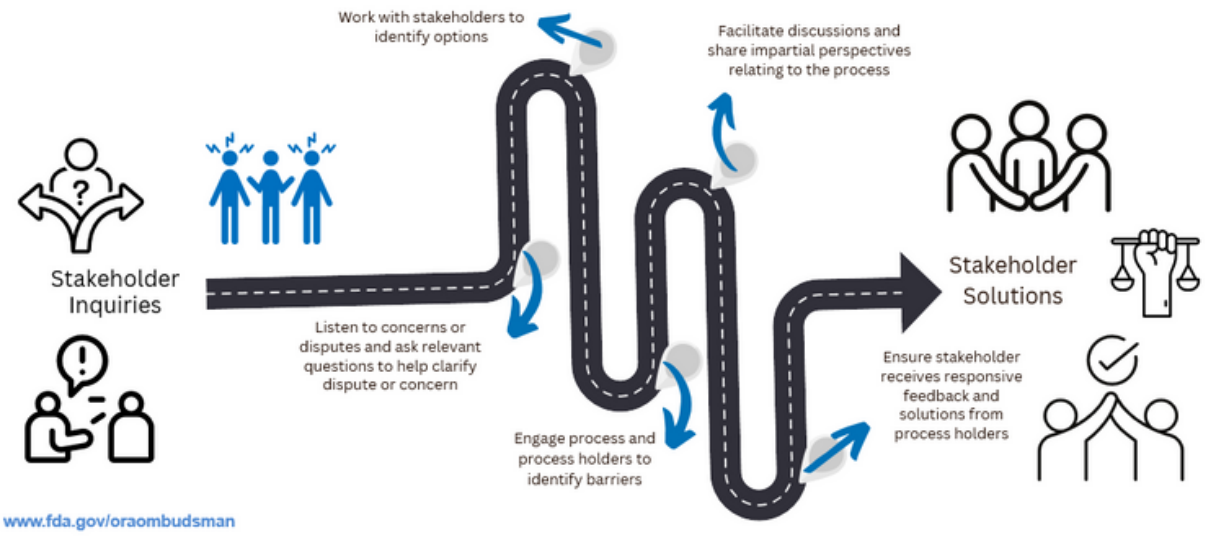
PROGRAM SUMMARY

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 the following core standards allow the ombudsman to be an advocate for fair processes and to assist external and internal stakeholders of ORA:



The OOP is a dedicated resource for stakeholders, offering guidance in navigating unresolved issues and concerns within ORA. When stakeholders have exhausted other channels, the OOP provides an informal pathway to find solutions.

Navigating a Path to Resolution



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

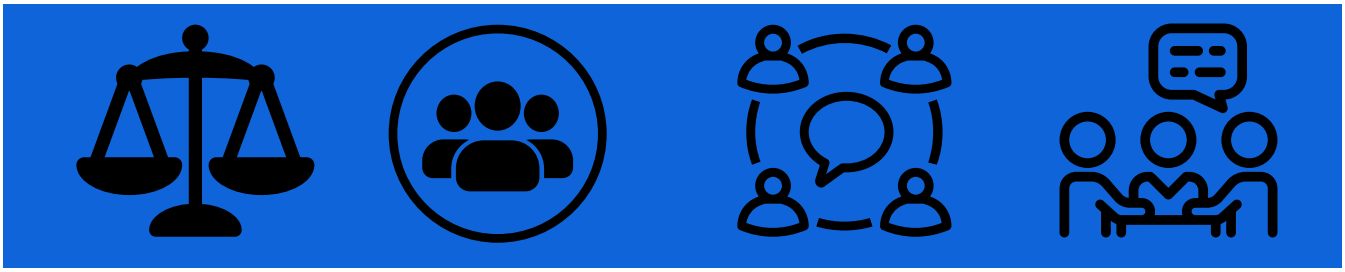
It's important to note that the OOP complements the existing mechanisms in place for addressing stakeholder concerns. The OOP Ombudsman works alongside these channels, providing an additional avenue when other routes have been exhausted. The program's commitment is to facilitate constructive dialogue, review relevant information, and find creative solutions that benefit all parties involved.

INQUIRY SUMMARIES 1.0

The OOP receives and informally responds to inquiries reported by ORA stakeholders. The term inquiry is used because some issues or concerns raised would not be considered disputes or complaints. The OOP Ombudsman reviews inquiries in an informal, unbiased manner and offers advice and facilitates the resolution process. As such, the OOP Ombudsman does not have decision-making power or the authority to force anyone to take action.

The OOP helps stakeholders find the right place within the agency to address their questions, assists in resolving disputes informally, and provides information about processes and mechanisms for dispute resolution, including disagreements between regulated industry and ORA, as well as differences of regulatory opinion among staff. Below are examples of how the OOP fulfilled this role in CY22.

Facilitating Communication between Internal Staff and Stakeholders – OOP commonly facilitates conversations with stakeholders and internal staff. In CY22, OOP also shared skills and techniques of facilitation with staff that requested assistance. The OOP assisted 38 internal staff members by brainstorming options for communication or providing an objective, neutral perspective on proposed communication efforts with stakeholders. Due to the nature of these interactions, the ombudsman spends a significant amount of time in this role. The OOP 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 ORA or other FDA officials.

Facilitating internal and external discussions.

Connecting Stakeholders to FDA/ORA Resources – OOP received 72 requests for the appropriate contact in CY22. These requests varied by stakeholder profile. Manufacturers, specifically those who were small food businesses, requested information relating to labeling exemptions, understanding risk elevations of CGMPs, and finding or using an ORA resource available at FDA.gov. States and other federal government agencies usually requested appropriated contact information for a process question or wanted to pass along information relating complaints they have received from their constituents. OOP actions for these inquiries included educating the stakeholder on ORA procedures, facilitating connections with appropriate contacts, and providing information that allowed the stakeholder to make an informed decision. The requests for appropriate contact is consistently a frequent concern as shown by Figure 1: Yearly Comparison of Most-Frequent Concerns.

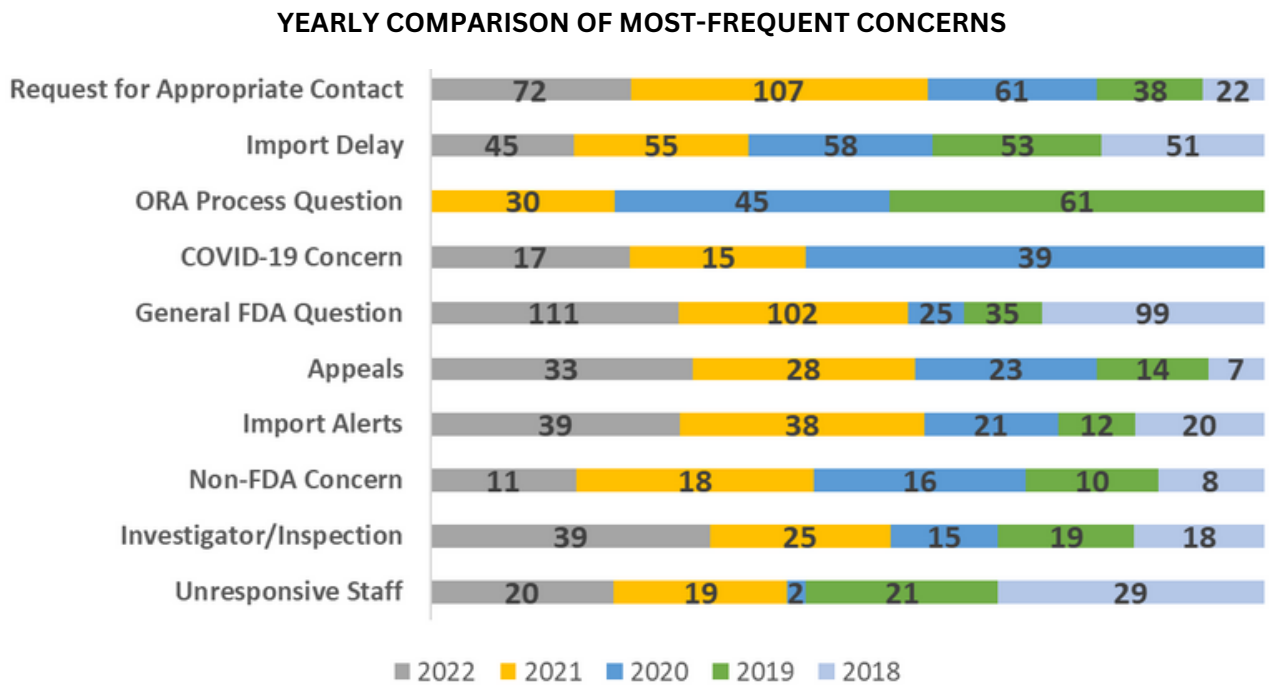


Figure 1: Inquiry Yearly Comparison CY 18 - CY 23

Clarifying Uncertainties in Correspondence – Stakeholders both foreign and domestic, receive periodic correspondence from ORA via email. This correspondence may announce inspections, request information, or may be an administrative advisory notification. Stakeholders reported concerns that some correspondence received may not have been legitimate or was the initiation of a scam. The OOP assisted 32 stakeholders in clarifying the correspondence process, facilitated communication between individuals and ORA staff, and helped to address concerns. In some instances, if the stakeholder did not seek confidentiality, information was shared with the ORA criminal investigatory team. OOP consistently receives inquiries from regulated industry, individual consumers and third-party representatives, such as lawyers and consultants. See Figure 2: Yearly Comparison of Stakeholders Categories.

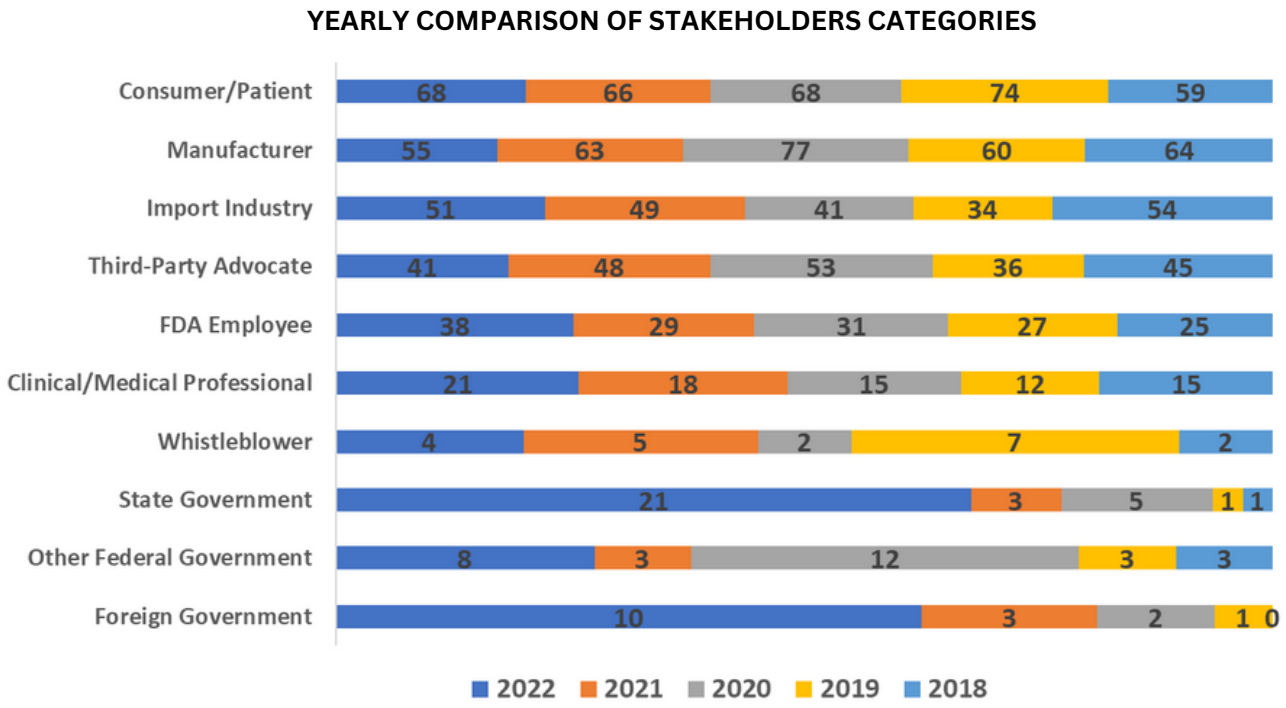


Figure 2: Stakeholder Yearly Comparison CY 18 - CY 23

Assisting with Recall Questions and Concerns – The ongoing recall of breathing devices made by Philips caused many consumers to contact the OOP. Consumers had questions about safety notices issued by the FDA and requested assistance in determining who to contact when they were not getting responses from the manufacturer. The OOP provided information to 26 consumer stakeholders on the consumer complaint process, resolved any questions about safety notices, and referred inquirers to various resources, such as the Freedom of Information Act webpage and MedWatch Voluntary Reporting Form.

RECOMMENDATIONS

The inquiries received by the ORA Ombudsman Program are sorted into three categories: General Inquiry, Direct Assistance, and Disputes. General inquiries do not include a process complaint or dispute of any sort. Direct assistance inquiries are complaints from external stakeholders or a request assistance in connecting stakeholders with the appropriate contact in ORA. Dispute inquiries are disagreements or challenges to a decision or action taken or not taken according to a related process.

Based on a review of these inquiries and input from the customer satisfaction survey, the OOP offers the following recommendations for potential process improvements to address stakeholders' concerns.

(1) Consider the creation of cross-functional process improvement teams

Stakeholders who request direct assistance have expressed dissatisfaction with the conflicting information they receive or review from different teams with ORA and FDA. This problem generates a significant number of complaints and often leads to disputes. Creating cross-functional process improvement teams may be a useful strategy to address this issue. These teams could evaluate feedback from stakeholders who encounter conflicting information from different offices or teams within ORA and FDA. While cross-functional process improvement teams may not provide an immediate solution, they can help to break down silos and promote overall communication across the organization.

(2) Evaluate the need to increase pathways of informal communication

The general inquiries received by ORA indicate that stakeholders are seeking better connection and engagement regarding policies or processes that are not well understood. Stakeholders have expressed their difficulty in navigating FDA and ORA resources online and understanding the information provided, which is a common issue. This problem is particularly prominent when there are changes in policies or operations. To address this concern and prevent conflicts and miscommunications, evaluating and establishing additional pathways for stakeholders to voice their concerns and promote two-way communication is recommended.

(3) Evaluate the need to create a point of contact listing by responsibilities

Specific stakeholder groups such as small businesses and consumers strongly recommended improving the ORA Field Leadership Contacts list. Currently, the list provides job titles without explaining the specific responsibilities of each individual. To address this, this recommendation is to add detailed information about each person's responsibilities to this listing. This will help our stakeholders easily identify the appropriate point of contact for their concerns and enable staff to provide more timely feedback.

OUTLOOK FOR 2022

The OOP will continue to accomplish milestones toward the overarching goals guiding the program. In summary, the goals guide the program to provide timely relevant information to facilitate conflict resolution while expanding education, communicating systematic issues, and demonstrating leadership in the ombudsman practice.

For CY 23 the following milestones will be developed and implemented:

(1) Expand education and understanding of the ORA Ombudsman Program

- Development of “Ask an Ombudsman” web/video quarterly series
- Analyze and publish in CY24 Annual Report r survey unattributed feedback results and recommendations

(2) Provide relevant and timely information to all ORA stakeholders and partners

- Close 92% of Ombuds inquiries annually
- Determine resources to upgrade the efficiency of Ombuds Program data capture systems

Program Years 2017 - 2022

1705
Stakeholders Assisted

2100
Concerns Facilitated

For assistance or more information:

FDA.gov/ORAOmbudsman

844-871-4536

ORAOmbudsman@fda.hhs.gov