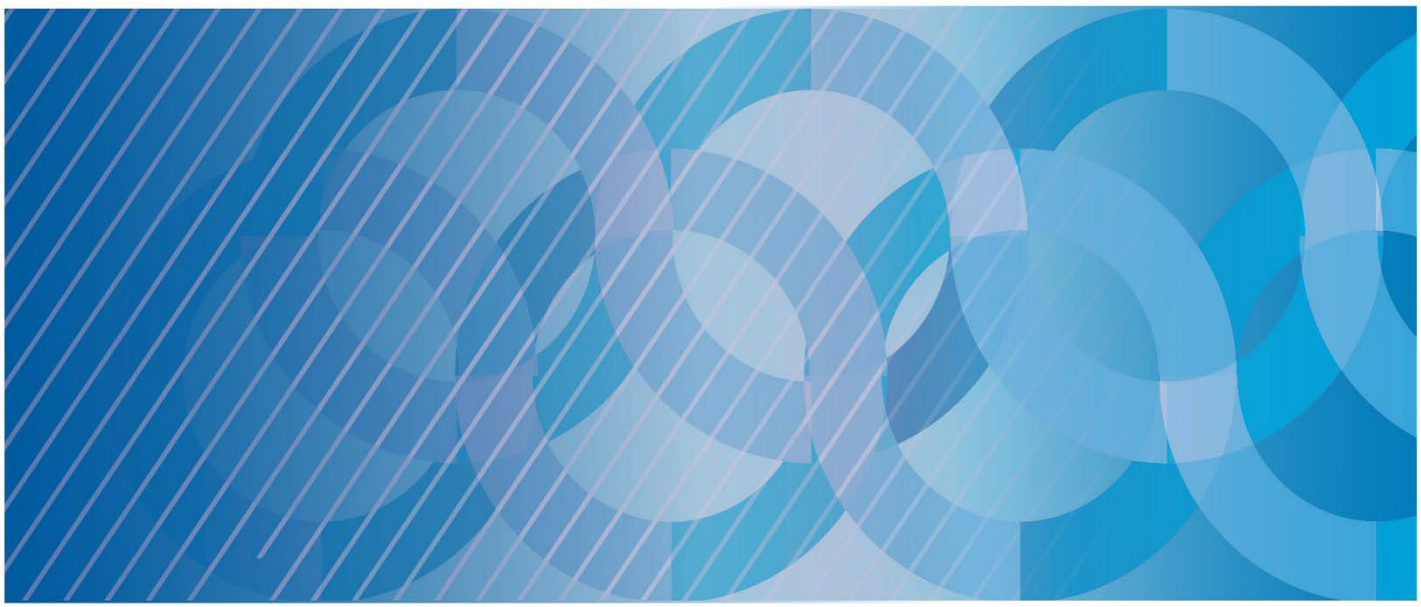
OFFICE OF REGULATORY AFFAIRS
OMBUDSMAN PROGRAM



ANNUAL REPORT

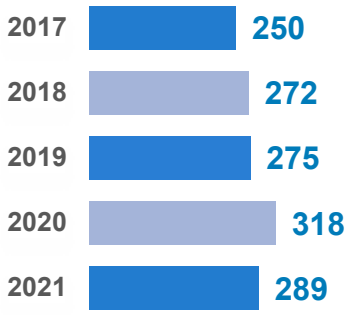
CALENDAR YEAR **2021**

U.S. FOOD & DRUG ADMINISTRATION

ORA OMBUDSMAN PROGRAM

CY21 Numbers and Stats: Quick Facts

INQUIRY COMPARISON 2017 - 2021



289
New inquiries in 2021

9%
decrease from 2020

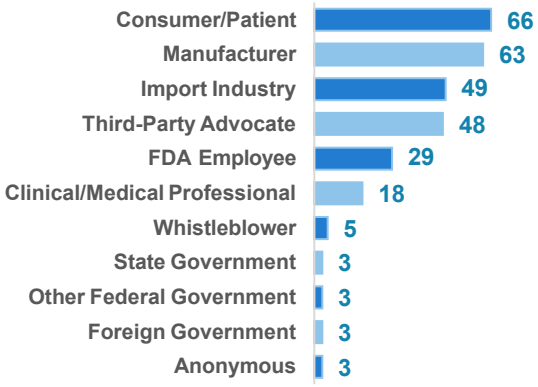
INQUIRY STATS 2021

98% of inquiries were addressed and closed

8 inquiries were brought forward from 2020, totaling **297** inquiries processed

78% of Initial inquiries were received via email

STAKEHOLDERS

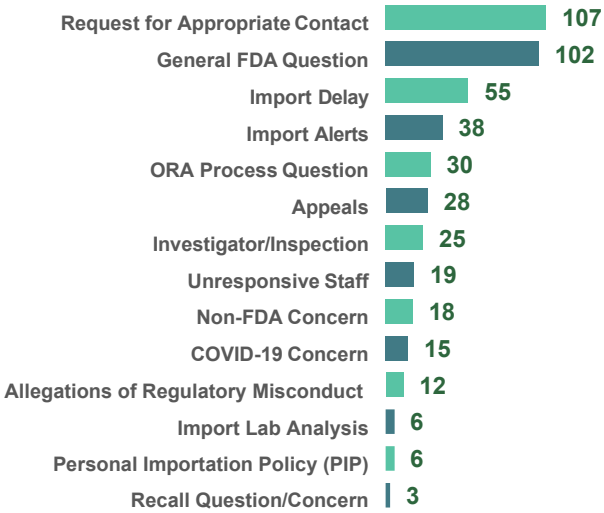


90% of inquiries are from external stakeholders

Most active engagement

- Consumer/Patient
- Manufacturer
- Import Industry

REASONS FOR INQUIRIES



85% of inquiries involved **2** or more concerns

Most common issues

- Appropriate contact information could not be located by stakeholder
- General FDA question that stakeholder could not find after multiple attempts to locate
- Stakeholder requested assistance related to import entry delay

COMMUNICATION STATS

1,748
Emails

234
Number of stakeholders engaged during outreach

13,232
Number of visitors to the Ombudsman website

2,540
Twitter Impressions

2021 YEAR IN REVIEW

OMBUDSMAN MESSAGE

Erica Katherine
ORA Ombudsman

The ORA Ombudsman Program (OOP) Annual Report summarizes the major functions and activities of the ombudsman in calendar year 2021 (CY21). The OOP enhances ORA operations by serving as a confidential, neutral resource to improve communication channels, resolve disputes, and foster positive relationships with ORA stakeholders. To learn more about the OOP, please visit the ORA Ombudsman webpage.

On July 1, 2021, the OOP function was transitioned from the Office of the Associate Commissioner of Regulatory Affairs to the Office of Partnerships and Operational Policy. This alignment allows the OOP to continue to provide an informal mechanism for external partners to provide confidential feedback and express concerns, and to promote fairness and consistency within the operational policy of ORA.

This report discusses the unique challenges that remained as the COVID-19 pandemic continued throughout CY21, and highlights milestones the program has achieved. The OOP's overarching goals have guided the program to informally find solutions to issues raised by ORA's external stakeholders and facilitate communications between ORA employees and stakeholders. The OOP used outreach and education to help both sides become more aware of each other's needs. See page 8 for a listing of the overarching goals and future milestones. In addition to regular functions, the OOP:

- Developed and published a one-page flyer on the internal and external OOP websites to increase collaborative communication with stakeholders and other programs.
- Developed and published a Frequently Asked Questions (FAQ) webpage in the external OOP website that addresses stakeholders' most frequent concerns.
- Developed and delivered a virtual "office hours" for ORA stakeholders to identify barriers in communication and to encourage cooperation during the processing of informal disputes.
- Published the 2020 annual report in the first quarter of 2021 documenting most-frequent concerns from stakeholders and providing a thematic summary of inquiries and recommendations.

In CY21, the OOP supported and facilitated the resolution of 464 concerns raised by 289 stakeholders. Through training and virtual outreach initiatives, an additional 234 stakeholders received information about the existing communication channels in ORA that are available to resolve their concerns and how and when to contact the OOP.

Ombudsman Program Summary CY21

Inquiry Totals and Outcomes

The total number of inquiries in 2021 declined from 318 to 289 compared to 2020. Increases and decreases in the number of inquiries may not necessarily indicate a reduction in concerns in a specific area, merely the number of stakeholders seeking the ombudsman's assistance. However, understanding the types of concerns across various inquiry categories helps the OOP alert ORA leaders and management about the potential impact of specific issues raised by its stakeholders while maintaining the confidentiality of each case. A comparison of the ten most-frequently-raised concerns versus inquiries across the past four calendar years (CY18 – CY21) is illustrated in Figure 1: Yearly Comparison of Most-Frequent Concerns from CY18 to CY21.

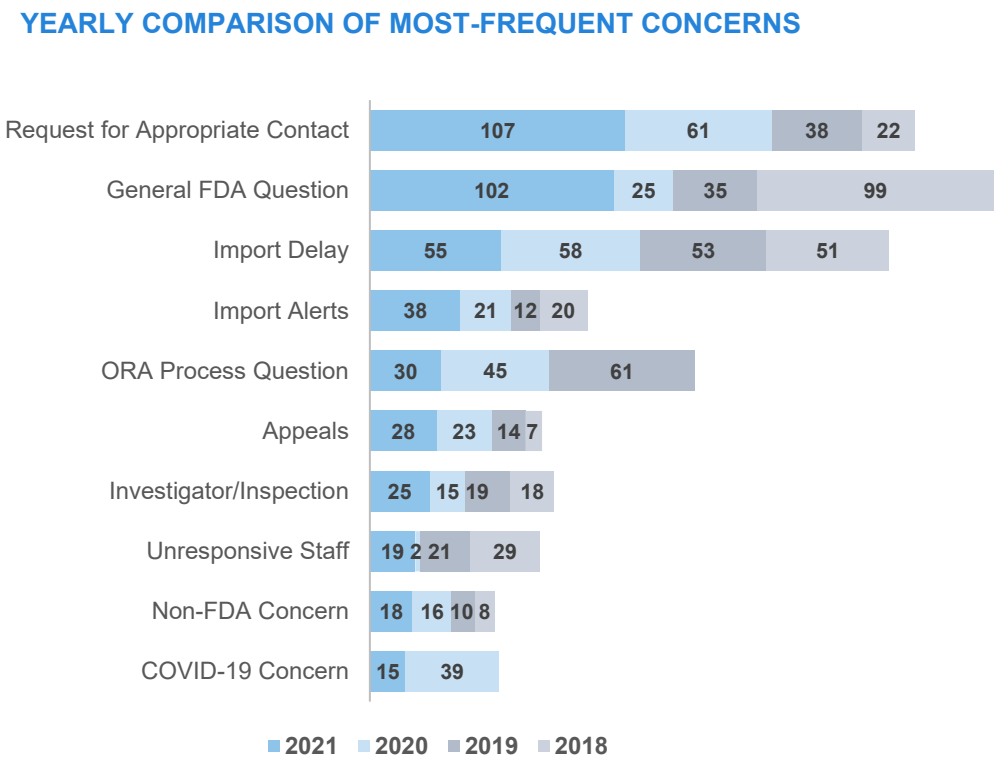


Figure 1: Yearly Comparison of Most-Frequent Concerns from CY18 to CY21

The inquiries received by the OOP are generally grouped into three outcome categories: stakeholders requiring information, direct assistance, or referral. Of the 289 inquiries received in 2021, 39% were resolved by educating the stakeholder on ORA procedures or by providing information that allowed the stakeholder to make an informed decision. Inquiries that required direct assistance through the facilitation of dialogue, shuttle diplomacy, feedback upward, or option recommendation were 33% of total inquiries. The ombudsman spends the vast majority of time and effort to address direct assistance inquiries that require multiple communication points of contact, additional research, and analysis. The remaining portion of inquiries in 2021 were referrals to internal or external parties (24%) and inquiries that were withdrawn or carried over into 2022 for further disposition (4%), listed as other. The figure on the next page shows a breakdown of the most frequent outcomes in 2021.

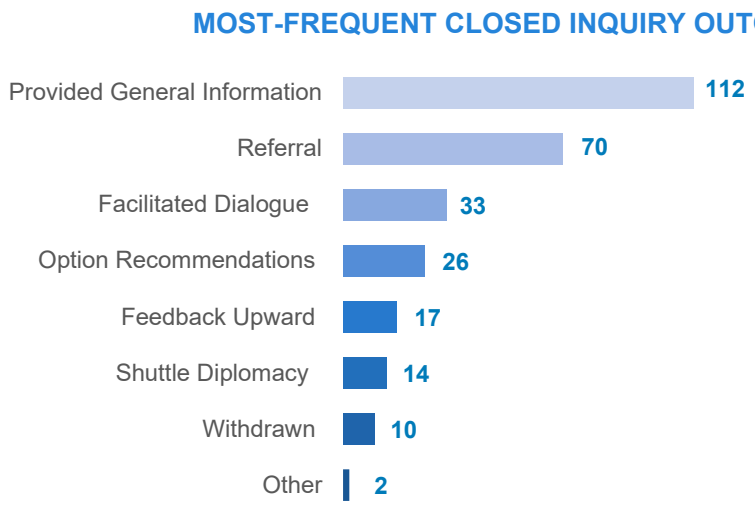


Figure 2. Most-Frequent Closed Inquiry Outcomes in 2021

Generally, stakeholders contacting the OOP have a primary and secondary concern. Of the 289 inquiries received in 2021, stakeholders raised a total of 464 concerns. Approximately 40% of these concerns were directly related to or involved a specific ORA program area. The figure below illustrates the number of inquiries by program/office in 2021. The Office of Enforcement and Import Operations maintains functions that have the most direct interface with the public and therefore received the highest number of inquiries.

Inquiries by Program/Office

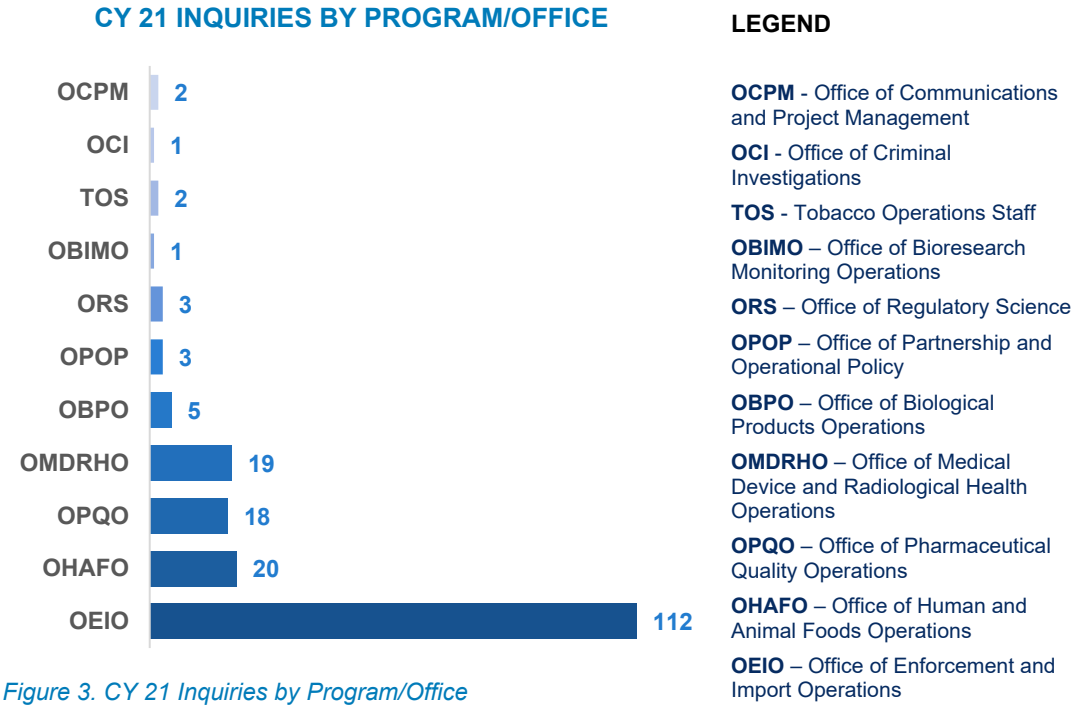


Figure 3. CY 21 Inquiries by Program/Office

Observations and Recommendations

The following observations and recommendations pertain to the three most frequent concerns: (1) obtaining the appropriate contact information, (2) general information request, and (3) import entry delays.

(1) Appropriate contact information

a. OBSERVATIONS: Major trends within requests for the appropriate contact information inquiries were manufacturers requesting contacts to obtain a remote assessment report, consumers requesting contacts for the iPLEDGE (program for managing the risk of isotretinoin); and consumers requesting contacts related to COVID-19 vaccines or tests. The iPLEDGE and COVID-19 related inquiries were referred to sources external to ORA for resolution. Requests for remote assessment reports related largely to the voluntary programs initiated for medical device and human food firms. A Remote Regulatory Assessment (RRA) is an evaluation by ORA of a firm's compliance with regulations or conformance with application submissions that is performed remotely. FDA launched a voluntary program in response to ongoing challenges presented during the global pandemic. Many of the requests for appropriate contacts were in the months of May and June, and as information became more widely distributed, requests subsided with no requests noted during the months of September through December.

b. RECOMMENDATION:
   - Consider the need for continued distribution of information internally and externally regarding RRAs so that there is clear universal knowledge of the program and appropriate contacts for questions.
   - Observations were not made for the iPLEDGE inquiries as those were referred to other FDA contacts for resolution.

(2) General requests

a. OBSERVATIONS: Stakeholders contact the ombudsman to either ask for help to locate guidance information for a variety of topics on FDA.gov or request information relating to complaints, food labeling, food manufacturing, and food recalls. All but two of these requests were referred to sources external to ORA for resolution.

b. RECOMMENDATION:
   - Evaluate the need for a revision to the Contact ORA landing page. Consider adding a "For Consumer" link to include answers to frequently asked questions, i.e., "How to get a copy of my complaint file?" This will allow consumers/patients to become more familiar with processes and to know what to expect when contacting FDA ORA.
   - Evaluate the need for a revision to the Contact ORA landing page, "For Industry" link. Consider adding flow diagrams or charts to this link describing the process framework for most frequently requested processes such as imports, recalls, inspections, and enforcement actions. Providing this information will especially help industry new to FDA regulation and small businesses become more familiar with processes within FDA ORA.

(3) Import entry delays

a. OBSERVATIONS: The Import Program is the most public facing within ORA, and in 2021, the program reviewed a total of 48.11 million entry lines of product intended for domestic distribution. Inquiries about holds or delays of import entry processing were commonly raised by two types of stakeholders – manufacturers and consumers – who were inquiring about an imported product delay, Import Alert, import lab analysis, and the Personal Importation Policy (PIP). As shown on Figure 1: Yearly Comparison of Most-Frequent Concerns of this report, "Import Entry Delay" is annually a frequent concern. All consumer inquiries also needed general information about the import process and available options after FDA detained an imported item. The majority of manufacturer inquiries were from small business owners who needed general information about the import process. To address these inquiries, the OOP provided information that is publicly available on FDA.gov; however, these individuals are often not able to find or understand the information enough to provide an appropriate response to the Notice of FDA Action issued for the shipment.

b. RECOMMENDATIONS:

- Evaluate the need for facts sheets that target basic steps for consumers and small businesses related to what happens when your shipment is delayed by a hold or is subject to a detention.
- Consider resources and availability of outreach activities to include virtual webinars or videos for local small business associations that can be used as a continual resource.
- Consider adding to the Notice of FDA Action a link to Detention & Hearing.

Ombudsman Outreach and Process

One of the two primary objectives of the OOP is to improve communication between ORA employees and stakeholders through outreach and education. External outreach and education actions implemented by OOP include:

Speaking Engagements – Opportunities to connect with groups or a group's membership via in-person conferences, conference calls, or webinar to share about the ombudsman as a resource.

Office Hours – "Office hours" at conferences, where attendees can meet with the ombudsman individually or in small groups to learn more about the OOP and receive assistance with their process concerns.

Social Media – Offering information throughout the year directed at the regulated industry and stakeholders at large through the OOP's webpage and the ORA Twitter account while promoting the OOP annual report, Ombuds Day, and the ombudsman profession.

Additional Opportunities – OOP seeks opportunities to increase awareness and elevate the visibility of the services we provide in ORA. Opportunities sought in CY21 included contributions to internal workgroups and providing information about the OPP via engagement in professional ombudsmen organizations.

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. The ombudsman is an advocate for common-sense solutions bridging the gap through procedural misunderstandings and disputes. Below are examples of the ombudsman process:

> *An importer is not sure of what to do after their shipment was detained. They did not agree with, or fully understand, the FDA notice from the ORA Import Division. The importer stated that attempts to gain additional information were not successful. The ombudsman's review of this matter revealed three primary issues. The first issue was unresponsive communication. The importer stated several emails sent went unanswered. The second issue was disputed information/lack of understanding of the violation listed on the FDA notice. The FDA notice listed an unapproved drug violation, and the importer was not sure how or why this was related to the food product being imported. The third issue was based on the importer's lack of understanding the import process and thus failure to respond appropriately with sufficient detail to the emails received from the ORA Import Division. Based on this review of the matter, the ombudsman provided information about the import process and presented to the importer options available for their next steps towards resolution. The importer opted for assistance having a facilitated discussion with the ORA Import Division. At the closure of this inquiry, the importer fully understood the charges and was clear on how to proceed with the entry. This interaction also helped the importer to have the necessary information for clearance of future shipments and allowed the ORA Import Division to gain perspective on ensuring communications are timely and substantive.*

> *An ORA employee was having difficulties communicating the regulatory outcome of a case to a firm. Many of the interactions with the firm and the ORA employee were very contentious. The employee's supervisor requested help from the ombudsman to facilitate the next conversation with the firm. For this inquiry, the ombudsman asked the supervisor to provide the firm the information to contact the ombudsman directly. The ombudsman service is voluntary, and the ombudsman must ensure all parties agree with the ombudsman's involvement in a matter. The firm agreed to discuss the matter with the ombudsman, and for this situation, shuttle diplomacy was best suited to facilitate these discussions. The ombudsman acted as an intermediary to ensure both sides understood their counterparts' positions and interests. This interaction concluded with both the firm and the ORA Division reaching an agreement on a path forward for what corrections were needed and how to communicate more substantively during future interactions.*

Outlook for 2022

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. The following milestones will be developed and implemented in 2022:

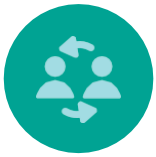
1. Continue efforts to broaden awareness of the ORA Ombudsman Program and its activities through direct engagement with regulated industry and ORA staff.
   - Development of quarterly reporting of total number of inquiries and demographics to program management
   - Development of a strategic engagement plan to increase facilitation of industry relationships through the OOP by raising awareness with external stakeholders and the service of timely resolution of process issues.

2. Provide relevant and timely information to all ORA stakeholders and partners that facilitates the resolution of conflict and promotes transparency, fairness, and collaborative communications.
   - Develop customer satisfaction survey to obtain feedback about the efficiency and effectiveness of Ombuds Program
   - Close 90% of Ombuds inquiries annually
   - Evaluate the need to upgrade the efficiency of Ombuds Program data capture systems

ORA OMBUDSMAN PROGRAM

CORE STANDARDS

Independence



Informality

Impartiality

Confidentiality
(when warranted)

Program Years 2017 – 2021

1,404

Stakeholders Assisted

1,675

Concerns Facilitated

For assistance or more information please visit
www.FDA.gov/ORAOmbudsman