OFFICE OF REGULATORY AFFAIRS

OMBUDSMAN PROGRAM

ANNUAL REPORT

CALENDAR YEAR **2020**

Ombudsman Message

A Year in Review

On behalf of the FDA Office of Regulatory Affairs (ORA) Ombudsman Program (OOP), I am pleased to present this annual report describing the activities of the ombudsman for the calendar year, January 01 through December 31, 2020.

The 2020 reporting year presented unique challenges as the nation navigated through a global pandemic and a period of social change. As an ombudsman, it is inherent to have the ability to adjust in times of uncertainty to determine the best way to assist stakeholders and to provide requested information. In consideration of these significant events, you may note some differences throughout this year's report.

Based on feedback and direct requests from internal and external stakeholders, this year's report describes actions taken by the OOP, and contains specific information about the role of the ombudsman along with examples of feedback based on stakeholder inquiries. Like last year, the report is formatted into three major sections: *Ombudsman Practice*, *Inquiry Data and Observations*, and *Going Forward*. The *Ombudsman Practice* section describes in greater detail the activities of the ombudsman role and addresses the additional information requested about the role. The *Inquiry Data and Observations* section includes charts and graphical representations of data categories developed from inquiries received by OOP. The *Going Forward* section reports on progress on OOP goals and planned milestones for 2021.

Erica Katherine, Ombudsman

This report also describes how objectives of this program were sustained during the COVID-19 pandemic considering both work and travel constraints. Engagement with stakeholders is a major objective of OOP and the report outlines steps taken to achieve this priority. Highlights from this year include:

- new internal engagement activities provided to ORA staff
- development of an external video published on the ORA Ombudsman webpage to assist external stakeholders to learn more about the role of the ORA ombudsman
- the development of real-time anonymized feedback to ORA management that will assist in the assessment of emerging topics.

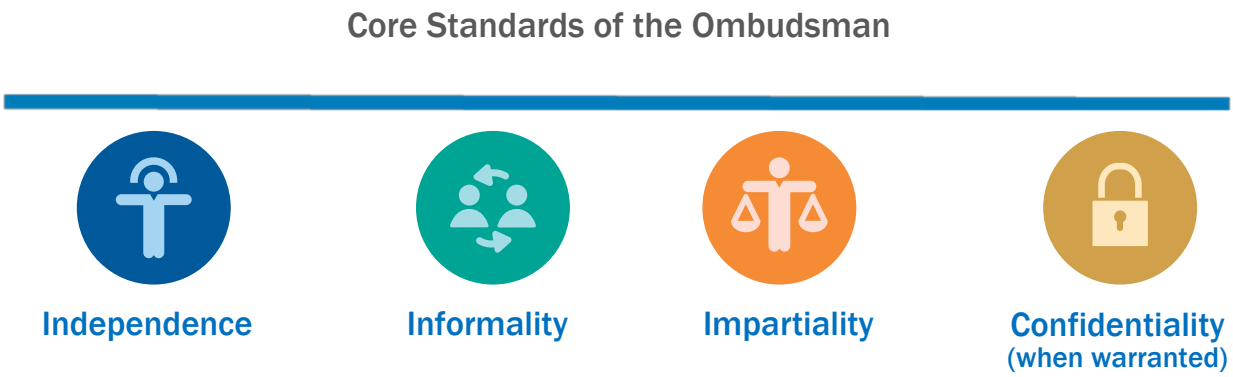
OOP will continue to actively seek engagement with stakeholders and promote transparency relative to ORA's activities. As policies and procedures may need to evolve quickly to ensure the protection of public health during challenging times, OOP will continue to be an advocate for fairness of process. The ombudsman program has and will continue to honor that commitment to ORA stakeholders in 2021.

Ombudsman Practice

Professional Standards of Practice

The ORA ombudsman and the OOP operate with two primary objectives to facilitate the resolution of process concerns that may arise from the mission driven activities conducted by ORA: 1) To informally find solutions to problems that arise with FDA's external partners, including industry, other governmental agencies and consumers; and (2) To improve communications between ORA employees and stakeholders through outreach and education, helping both sides become more aware of each other's needs.

The OOP maintains the principles of confidentiality, neutrality, informality, and independence, as drawn from the Administrative Conference of the United States (ACUS) report "Recommendation 2016 – 5: The Use of Ombuds in Federal Agencies." Adherence to these core tenets and standards allow the ombudsman to be an advocate for a fair process and to assist external and internal stakeholders of ORA:



Independence – To ensure independence and objectivity, the ombudsman does not report to any of ORA's six commodity-based programs offices. The ombudsman reports directly to the Office of the Associate Commissioner for Regulatory Affairs (ACRA) and publishes an annual report to all stakeholders.

Informality – The services offered by the OOP are voluntary and are not provided to initiate any formal proceedings against the ORA or FDA. The use of the OOP is not a substitute for formal procedures. The ombudsman cannot compel action or compliance.

Impartiality – The ombudsman maintains a neutral position and does not represent or act as an advocate for any person or entity in a dispute with ORA. The ombudsman is an advocate for a fair process, considers the rights of all parties, and does not take sides.

Confidentiality – Upon request, communication with the ombudsman will be considered confidential. The ombudsman does not share the identity of the stakeholders who contact OOP with others, except where there is: imminent risk of serious harm to persons or property;

allegations of fraud, waste, or abuse; specific permission given to waive confidentiality; or a requirement by law.

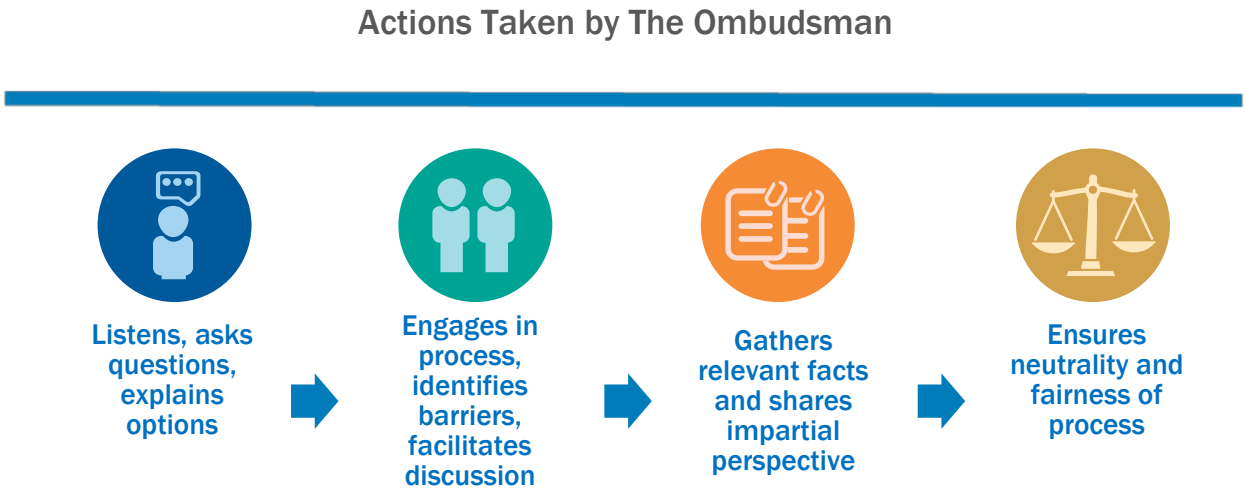
Role of the Ombudsman

The ombudsman fulfils the primary objective of OOP and supports the mission of ORA by helping stakeholders to identify and evaluate options; explaining the appropriate process for resolution; when possible, referring concerns to the appropriate office or program management, and monitoring the outcome of the inquiry. When a stakeholder contacts OOP, it is termed an inquiry. Inquiries often involve issues, or concerns that a stakeholder could not resolve through normal channels, could not determine the proper avenue for handling the concern, or requests to discuss a matter confidentially. Monitoring the outcomes of OOP inquiries assists the ombudsman to make responsive suggestions to mitigate any thematic issues from recurring in the future. The ORA ombudsman also takes a proactive approach to resolve stakeholders' concerns by conducting internal and external outreach and education. The OOP outreach and education efforts also enhance communication between ORA and external stakeholders and improve transparency regarding the agency's compliance and investigation processes. The ombudsman finds informal solutions for problems and concerns expressed by stakeholders within OOP inquiries, by providing a neutral perspective and maximizing opportunities for collaboration within ORA and stakeholder relations, while advocating for fairness, efficiency, and effectiveness of internal ORA operations.

When contacting the OOP for assistance, you can expect the ombudsman to listen to your issue; ask pertinent questions; review relevant rules, policies, and documents; provide feedback; and discuss available options. The ombudsman also acts as a source of information and referral to help address your concerns at the most appropriate level within ORA and FDA.

Requesting assistance from the ombudsman does not replace the mechanisms ORA already has in place to respond to the issues raised by its stakeholders. The ombudsman helps ensure that ORA's established policies and practices are implemented equitably and that ORA stakeholders have a resource to assist them with exploring and determining options to help resolve conflicts, problematic issues, or concerns. 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.



Education and Outreach

One of the two primary objectives of the OOP is to improve communication between ORA employees and stakeholders through outreach and education. Outreach and education activities are conducted in accordance with the ombudsman standard of impartiality by balancing outreach opportunities over time to ensure fairness of engagement with the external stakeholders and regulated industry. External outreach and education actions that OOP implemented in 2020 include:

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

Office Hours – OOP offered "office hours" at conferences where attendees can meet with OOP one-on-one or in small groups to hear about OOP and getting assistance with process concerns.

Social Media – OOP was actively engaged throughout the year with stakeholders and regulated community at large through FDA's LinkedIn, Twitter, and Facebook by promoting the OOP annual reporting, Ombuds Day, and the ombudsman profession.

Additional Opportunities – OOP sought opportunities to increase awareness and elevate the visibility of the services offered by the ombudsman and ORA. These outreach activities included participation in appropriate regulated industry events, professional conferences, and related activities that allow for engagement of professional colleagues and ORA stakeholders.

As with external outreach efforts, the OOP looked for ways to expand the methods to connect with internal stakeholders to share information about the role and highlight how the OOP can serve as a resource. Internal engagement included introductory meetings or presentations to new and existing staff, and introductory emails to new senior level staff. At the same time, OOP maintained a series of meetings with ORA leadership and staff of the divisions and offices,

whether weekly, monthly, bi-monthly, or quarterly. These regular engagements ensure the ombudsman can promptly connect with the right ORA and FDA contacts to address process issues, while also giving the ombudsman the opportunity to maintain awareness about current ORA activities.

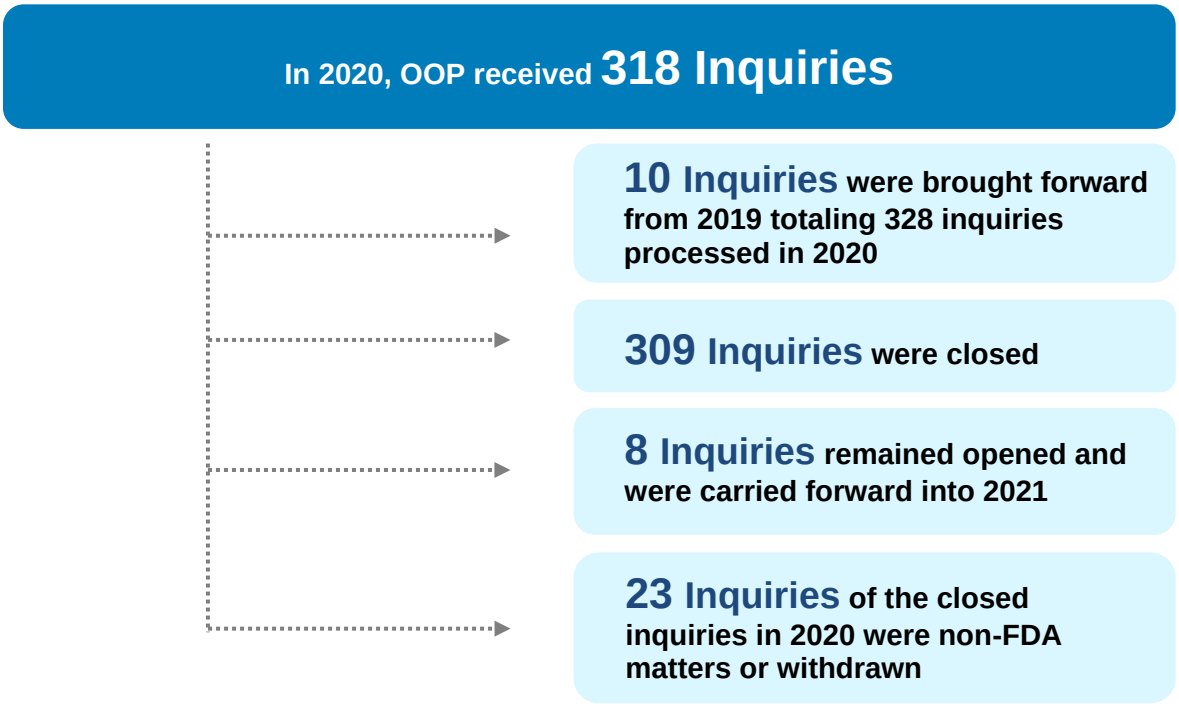
During the COVID-19 pandemic, the OOP offered varied ways to continue to connect with the ombudsman by scheduling flexible extended office hours to increase response times and allow direct engagement as requested. The OOP has discussed with industry and advocacy groups to review how the ombudsman could participate in conferences in a virtual format.

Inquiry Data and Observations

Inquiry Totals

In 2020, the OOP reviewed and responded to 318 inquiries. Figure 1 summarizes the disposition and outcome of inquiries submitted by both internal and external stakeholders. An inquiry is recorded whether the matter is within or outside the OOP mission and includes disputes, issues, concerns, complaints, and review requests. Telephone and email are the most common way of initiating contact with OOP.

Figure 1: Inquiry Totals 2020



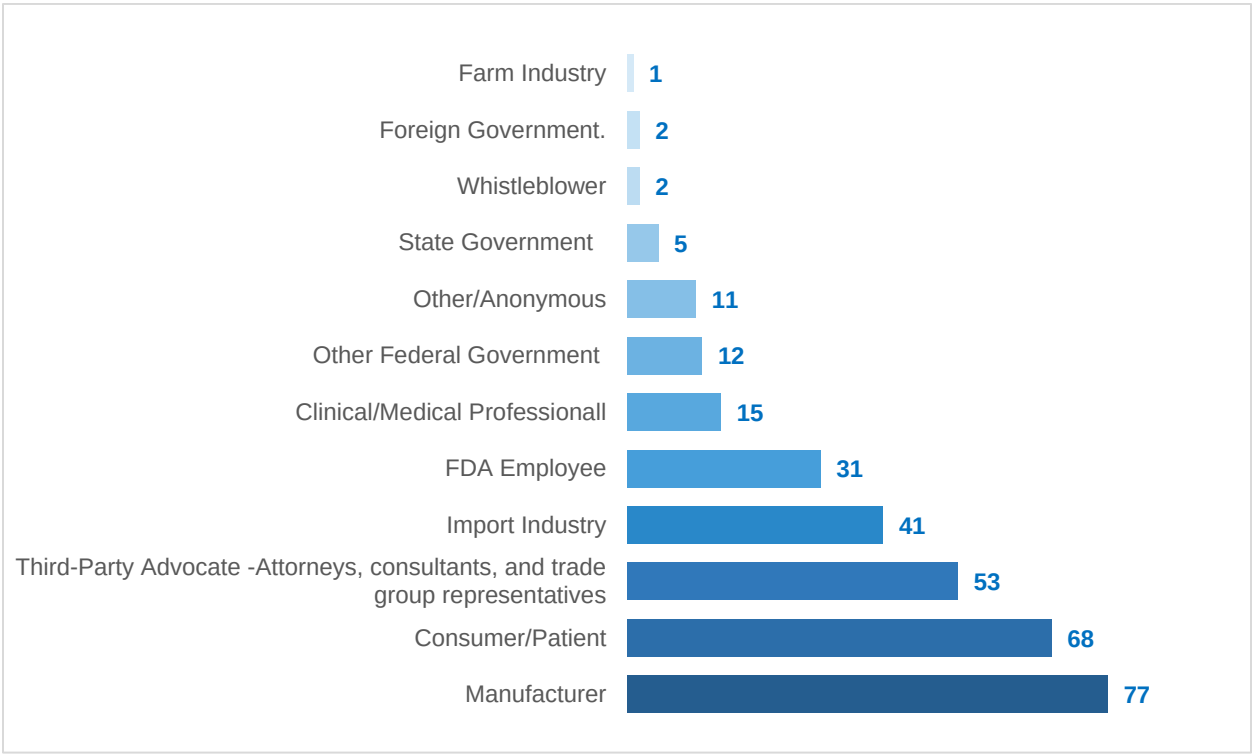
As shown in the figure below, the number of inquiries from 2017 to 2020 has remained mostly steady with a slight increase in 2020.

Figure 2: Inquiry Comparison 2017 – 2020

Stakeholder Profile

The OOP receives inquiries from many sources, including regulated industry, law firms, or consultants representing industry, advocacy groups, public and private research institutions, health care practitioners, consumers, and internal FDA sources, among others. The related issues or questions received can be of a regulatory, scientific, or administrative nature. The stakeholder categories within **Figure 3** were developed from inquiry information provided by the inquirer. An individual or business entity requesting assistance from the OOP is not required to provide any stakeholder category related information. Inquiring parties that chose not to provide this information are included in the "Other/Anonymous" category in Figure 3.

Figure 3: Stakeholder Contacts 2020

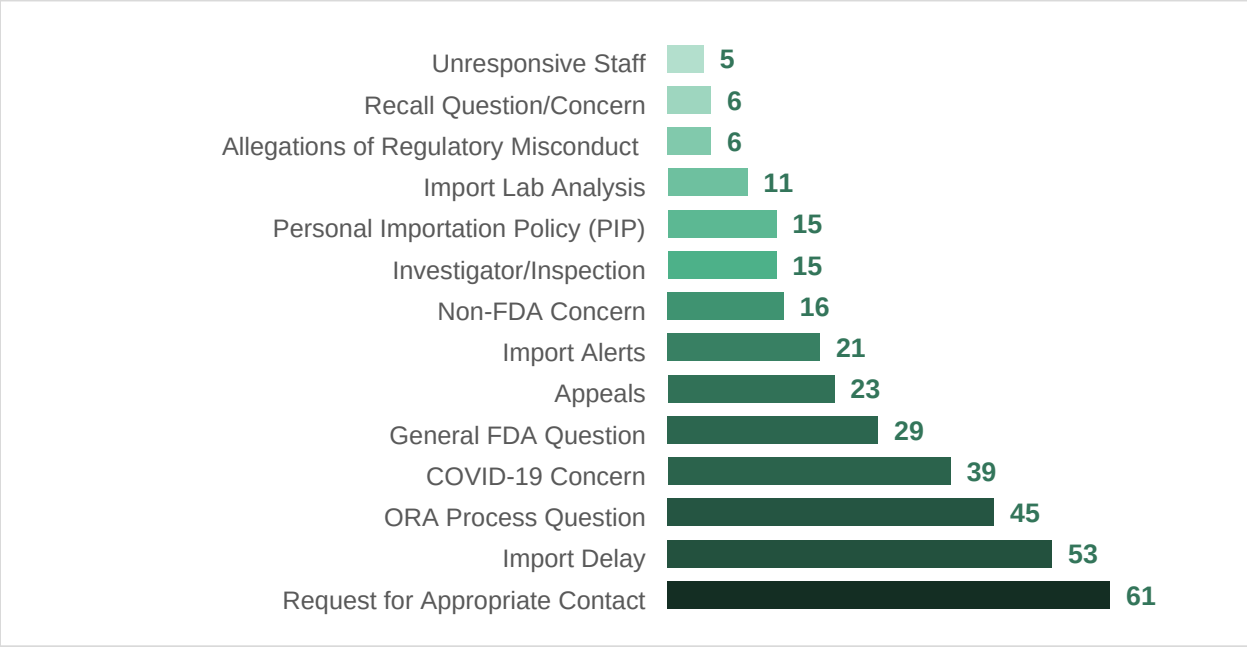


Category Type	Definition
Farm Industry	Farmers and farm-related industry professionals
Foreign Government	Individual employed by national government of a country other than the U.S. government.
Whistleblower	Individuals that report allegations of illicit activity
State Government	Individual employed by a state or local municipality
Other/Anonymous	Inquirer who does not self-identify or when it cannot be determined based on the related concern or dispute
Other Federal Government	Individuals employed by Federal Government other than FDA
Clinical / Medical Professional	Clinical research medical professional
FDA Employee	Employees of ORA other parts of FDA
Import Industry	Importers, exporter, brokers, and other trade professionals involved in the import industry
Third-Party Advocate	Attorneys, consultants, and trade group representatives
Consumer/Patient	General public and consumers
Manufacturer	Owners and employees of regulated industry

Inquiry Categories

The most frequent recurring areas of concern identified within the 2020 inquiry data are shown in **Figure 4**. The inquiry category areas of concern within this report were developed from data sorted and grouped directly from inquiries received in the 2020 calendar year.

Figure 4: Most Frequent Concerns 2020

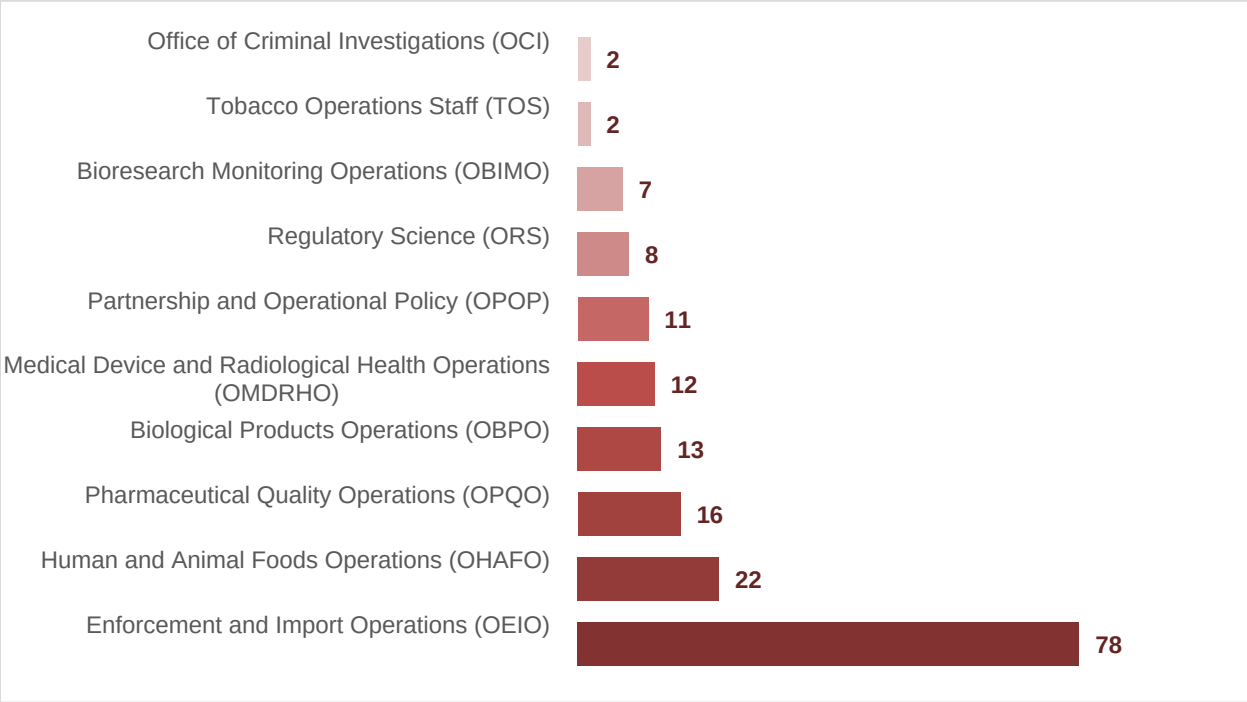


Category Type	Definition
Unresponsive Staff	Problems contacting staff that has not responded after at least one documented attempt by the stakeholder
Recall Question/Concern	Concern, process issue, or dispute related to an ongoing recall
Allegations of Regulatory Misconduct	Reported allegations against firms in the regulated industry, individuals, and FDA employees
Import Lab Analysis	Question or concerns related to a lab result or sampling issue
Personal Importation Policy (PIP)	Question or concern related to PIP
Investigator/Inspection	Question or concern related to an investigator or inspection
Non-FDA Concern	Issue not related to FDA regulated product or process (referrals)
Import Alerts	Question or concern related to an Import Alert
Appeals	Request for information on the appeals process within ORA or requesting assistance with a dispute where a formal appeal has not been initiated.
General FDA Question	Questions related to an FDA-related product or process not ORA
COVID-19 Concern	Question, complaint, or concern related to COVID-19 information or ORA related COVID-19 enforcement decision
ORA Process Question	Questions related to an ORA process not related to an import process or inspectional concern
Import Delay	Concerns related to an import entry on hold or detained
Request for Appropriate Contact	Issues with determining the appropriate contact or desire to discuss problems with current contact information

Inquiry Numbers by ORA Program or Office

To provide an understanding of how the inquiries received by OOP relate to ORA processes, **Figure 5** sorts the number of inquiries received in 2020 by the related ORA Program or Office.

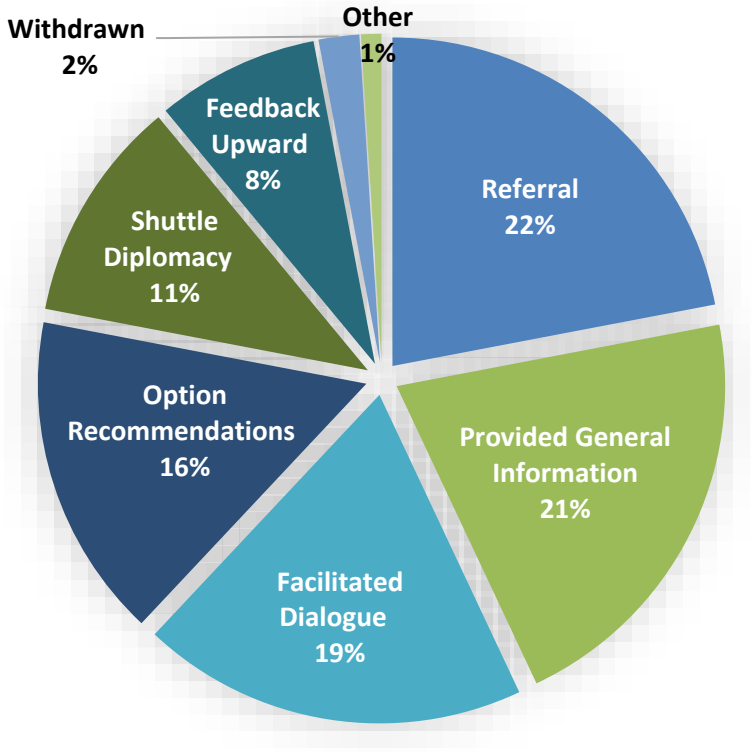
Figure 5: ORA Program or Office Inquiry Correlation



Closure Categories

Closure of an inquiry occurs when a solution is determined, the inquirer no longer requests assistance, all viable options are exhausted, or a formal process is initiated and concluded. An outcome that is facilitated in an equitable manner is the goal of an inquiry prior to closure. All inquiries are monitored until closure. The data in **Figure 6** shows the relative percentages of the defined common outcomes of inquiries closed in 2020.

Figure 6: Most Frequent Closed Inquiry Outcomes in 2020



Outcome	Definition
Referral	Closed inquiry after referral to another ombudsman or other resource within ORA or FDA.
Provided General Information	Inquiry closed by defining the steps for a specific ORA process.
Facilitated Dialogue	Inquiry closed after facilitated discussions with stakeholder and ORA.
Option Recommendations	Inquiry closed by providing education about administrative and policy options
Shuttle Diplomacy	A communication barrier was identified and closed using shuttle diplomacy.
Feedback Upward	Inquiry closed after connecting the stakeholder with the next level of management responsible for the process.
Withdrawn	Inquirer no longer requires assistance or does not respond after initial contact.
Other	Outcome was specific to a technical issue or not closed prior to the end of 2020.

Summary of Inquiries by Subject Area / Process

The reporting categories seen in **Figure 4** classify the types of issues for which stakeholders use ombudsman services and help to identify trends for consistent reporting. Another way to summarize the inquiries is to review the reporting categories to determine like processes or

subject areas. By consolidating like processes or subject areas, the inquiry category data reveals three major categories: (1) Import Inquiries, (2) COVID-19 Concerns, and (3) Informational Inquiries. Informational inquiries occur when a stakeholder requests information about a specific process or has concerns about a process. Within these three categories, each included a number of recurring secondary concerns. The consolidated reporting categories and secondary concerns related to those process or subject areas are listed below.

Import Inquiries
Import Delay/Import Lab Analysis/Import Alerts: (1) issues with quality of responses provided, (2) request appropriate contacts, (3) appeal review requests, (4) inconsistent private lab sampling instructions, and (5) responsiveness/timelines

COVID-19 Concerns
COVID-19 Concerns/Issues: (1) request appropriate contacts (2) recall and import alert concerns, (3) process/guidance concerns and (4) appeal review requests

Informational Inquiries
Appeals/Recall Concerns/General FDA/ORA Process Concerns: (1) issues with quality of responses provided and (2) request appropriate contacts

Capturing the data in this way provides specific areas of concern from stakeholders within a subject area and will allow for identification of processes to be evaluated by the corresponding process holders within ORA.

Thematic Summary of Inquiries

OOP's work to support ORA's mission while maintaining the ombudsman's principles of neutrality and independence during the pandemic took on several themes during 2020. A thematic view of the variety of issues addressed by OOP is captured below.

Feedback on Process to Review Quickly Emerging Topics - OOP provided real-time information to ORA management about stakeholder challenges and concerns in relation to the COVID-19 pandemic. OOP also facilitated meetings with different organizational units within ORA to assist stakeholders to determine next steps and solutions to emerging issues related to the COVID-19 pandemic.

Connecting State and Other Federal Agencies with ORA – OOP was contacted by state and federal agencies that had outdated contact information in reference to shared enforcement responsibilities and authorities with FDA. OOP was also able to connect the state and federal officials to the appropriate contacts within ORA to ensure the expected enforcement actions could take place quickly and effectively.

Working Closely with the Other FDA Ombudsmen – Working closely with other FDA ombudsmen is vital to ensuring stakeholders are directed to appropriate resources when referrals outside of ORA are necessary. During the COVID-19 more referrals were needed as many stakeholders were calling all resources to obtain the most current information related to their concern. OOP referred 12% more stakeholders to other sources in 2020 than in 2019 and

worked closely with other FDA ombudsmen to ensure stakeholders were directed to the appropriate resources.

Monitoring and Reviewing Appeals and FDA Guidance – Monitoring appeals and current guidance is a normal activity for an ombudsman; however, during the COVID-19 pandemic, this was especially challenging. As of the compilation for this report, FDA had published 72 guidance documents for industry, FDA staff, and other stakeholders related to COVID-19. Many of the guidance documents are directly related to enforcement and many ORA stakeholders requested appropriate contacts for questions or to discuss areas of concern. OOP helped to connect stakeholders to appropriate contacts and provided general information where appropriate. Guidance documents represent FDA's current thinking on a topic. Understanding the difference between guidance documents and compliance with the applicable statutes and regulations was a new challenge for some stakeholder types in 2020. Within this group of new stakeholders were importers and manufacturers (US distilleries and foreign facilities) of hand sanitizers. For these stakeholders it was important to know how to initiate an appeal or dispute when their opinions differed from FDA's interpretations. As ombudsman, I am not involved in the formal appeal process, however I monitor these requests to determine if the process functioned as described to the stakeholder. For 2020, there was a 91% increase in requests for appeal information (12 inquiries in 2019 and 23 in 2020). The most consistent topic within the OOP inquiries related to appeals was the manufacture and importation of hand sanitizers.

OOP Feedback

The OOP can be an advocate for common-sense solutions bridging the gap through procedural misunderstandings and disputes. Inquiry outcomes may not always meet the stakeholder's expectations. OOP received feedback in 2020 from stakeholders who had sought assistance from the ombudsman or attended an internal webinar presentation provided by the ombudsman. The feedback was received via email after an inquiry closure or via survey after a presentation. A few selected comments that describe closure outcomes are listed below:

Inquiry Closure Feedback

A clinical researcher stated: "*You kindly spoke on the phone with me last week and directed me to some helpful resources. I received assistance on my regulatory interpretation issue from one of the contacts you directed me to, so I wanted to thank you for your time and help. It is very greatly appreciated*"

A medical device manufacturer stated: "*FDA/CDRH reached out to me yesterday, and we are scheduled to have a teleconference on Thursday. Thank you so much for getting us point of contact with the Center*."

An importer stated: "*Excellent. Thank you, and thanks for the SUPER FAST response!*"

A food manufacturer stated: "*Thank you for assisting us to solve this matter.* [Name redacted] *received EIR and final response from* [name redacted]."

A medical professional stated: "*Thank you. Living proof that an ombuds enhances any organization.*"

A drug manufacturer stated: "*I just wanted to let you know that my facility has now received the EIR from our inspection in* [location redacted]*. I really appreciate your efforts to get this closed out formally."*

Outreach Feedback

All comments below were received from internal FDA employees via survey after a presentation.

"*Great, thanks for your help, you made my day ☺. I will make sure I always meet the FDA requirements. Appreciate your intervention.*"

"Thank you for your time today. Your perspective and suggestions were very helpful."

"Excellent and inspirational. I am proud to have you representing ORA as our ombudsman."

"I really enjoyed your presentation. I can see how you were trying to relate with your audience, and the use of sayings to drive the message was very effective"

"Great presentation! Prior to this presentation, I had little understanding of the ombudsman role, but I feel as though I'm much more informed. Thank you."

Going Forward

OOP established four overarching goals for 2020 that will guide the program moving forward. The following milestones were accomplished in 2020.

- **Expand education and understanding of the OOP.**
    - Revised and updated information for the ORA ombudsman external website to include an updated video that explains the role of the ombudsman and how the OOP is a resource for all ORA stakeholders.
    - Launched an internal OOP webpage as a new form of education and engagement for FDA internal staff to have a resource describing the types of internal inquiries handled by the OOP.
    - Developed content about the OOP that was added to the ORA New Hire orientation manual for continuing awareness about OOP.
    - Developed presentation series supporting good government practices to assist staff to identify barriers in communication with stakeholders and to encourage cooperation during processing of informal disputes. Presented series to all program offices within ORA to expand understanding of OOP services.
- **Continued to offer stakeholders a high, consistent level of service by demonstrating leadership in the ombudsman practice and profession.**
    - Finalized and implemented draft OOP workflow procedures developed in 2019.
    - Engaged in professional ombudsman organizations, trainings, meetings, and conferences, as permitted by program priorities, and budget.
- **Captured and communicated individual and systematic process issues to leadership and support resolutions by advocating for fair process solutions.**
    - Developed oral and written deliverables to streamline communication upward as early warning mechanism for potential systematic issues.
    - Virtually met with program managers, prioritizing time with those new to ORA.

Expanding on these goals for 2021, the OOP is planning the following milestones:

- Optimize communication workflow by completing an anonymized database of inquiries for tracking and trending.
- Create a virtual outreach plan to increase external stakeholder engagement.

- Develop a quarterly plan for management engagement.
- Develop a one-pager describing services offered by OOP and an FAQ.
- Explore expanding office hours to a virtual platform for outreach and education.

Contact the Ombudsman

You should contact the ORA ombudsman if you believe you cannot resolve a concern through normal channels, cannot determine the appropriate process for handling your concern, or if you require confidentiality. The ombudsman encourages all stakeholders to first attempt to resolve concerns or disputes with the ORA program division and if necessary, the program director of the division. If the issue is not resolved, that is the opportune time to contact the ombudsman.

The ombudsman reviews complaints or disputes and attempts to resolve them, usually through recommendations or mediation with the objective of achieving a fair outcome. You are also welcome to contact the ombudsman at any time to:

- Discuss this report
- Raise a process concern
- Discuss how to initiate an appeal
- Provide feedback or a suggested change for a process
- Discuss or schedule a presentation about the OOP

The ombudsman looks forward to the opportunity to address your concerns. See contact information for the ORA ombudsman below.

Email: ORAOmbudsman@fda.hhs.gov
Phone: 844-871-4536
Website: www.fda.gov/ORAOmbudsman