FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

ORA

Ombudsman

2019 Calendar Year Annual Report

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OVERVIEW OF THE ORA OMBUDSMAN PROGRAM (OOP)

Erica M. Katherine serves as Ombudsman within the OOP.

On behalf of the U.S. Food and Drug Administration (FDA) Office of Regulatory Affairs (ORA) Ombudsman Program, I am pleased to present this annual report describing the activities of the ombudsman for the calendar year, January 01, 2019 through December 31, 2019.

In support of FDA's implementation of the Food Safety Modernization Act, ORA established an ombudsman position to address resolving process issues that may arise from inspectional activities. Since its founding in October of 2015, the ORA Ombudsman and the ORA Ombudsman Program (OOP) has operated with two primary objectives to address this goal: 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.

As an ombudsman, I am committed to actively engaging with stakeholders, as well as promoting transparency relative to agency activities. It is my hope that you will find this Report to be of value in understanding the role of the ombudsman and the various areas where I provide assistance. The 2019 Annual Report is organized into three major sections: Standards of Practice, The Numbers, and Going Forward. The Standards of Practice outlines operating principles of OOP and includes definitions of principles used. The Numbers section includes charts and graphical representations of data categories developed from the inquiries received by OOP. The Going Forward section explains the newly developed goals for the OOP that will drive the direction of the program going forward.

The format and content for the OOP annual report is evolving to include feedback from internal and external stakeholders. I invite your suggestions for future editions of the annual report. You can provide any suggestions directly to me via Erica.Katherine@fda.hhs.gov, or any of the methods provided on the final page of this Report.

Thank you,

Erica M. Katherine

STANDARDS AND VALUES OF OMBUDSMAN PRACTICE

Independence

Informality

Impartiality

Confidentiality
(when warranted)

The ombudsman is a special kind of complaint-handling official who investigates complaints or disputes and attempts to resolve them, usually through recommendations or mediation. The ombudsman in the OOP is independent and abides by the ethical principles of confidentiality, informality, and neutrality. These principles are the cornerstone of the vision for the OOP and are described below.

Vision

To enhance ORA operations by serving as a resource (confidential when necessary) to improve communication channels, facilitate dispute resolution, educate, and foster positive relationships with internal and external stakeholders.

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 (OACRA) 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 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.

OOP PRACTICE BY THE NUMBERS

The ombudsman informally responds to "inquiries" that include disputes, issues, concerns, and complaints received by the OOP. The term inquiry is used because some issues or concerns raised would not be considered disputes or complaints. After determining the level of confidentiality desired by the stakeholder relating to the inquiry, the ombudsman engages the process related to the concern or issue to identify any barriers and facilitate further discussions. Once relevant facts are gathered and shared, the ombudsman can provide an impartial perspective with all parties to ensure neutrality and fairness of the process.

In 2019, the OOP reviewed and responded to 275 inquiries submitted by both internal and external stakeholders. On average, each inquiry received generates six additional communications or contacts. Using this average, the total number of communications or contacts generated to process 275 inquiries was 1,650.

Stakeholder Profile

The OOP receives inquiries from many sources, including the 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.

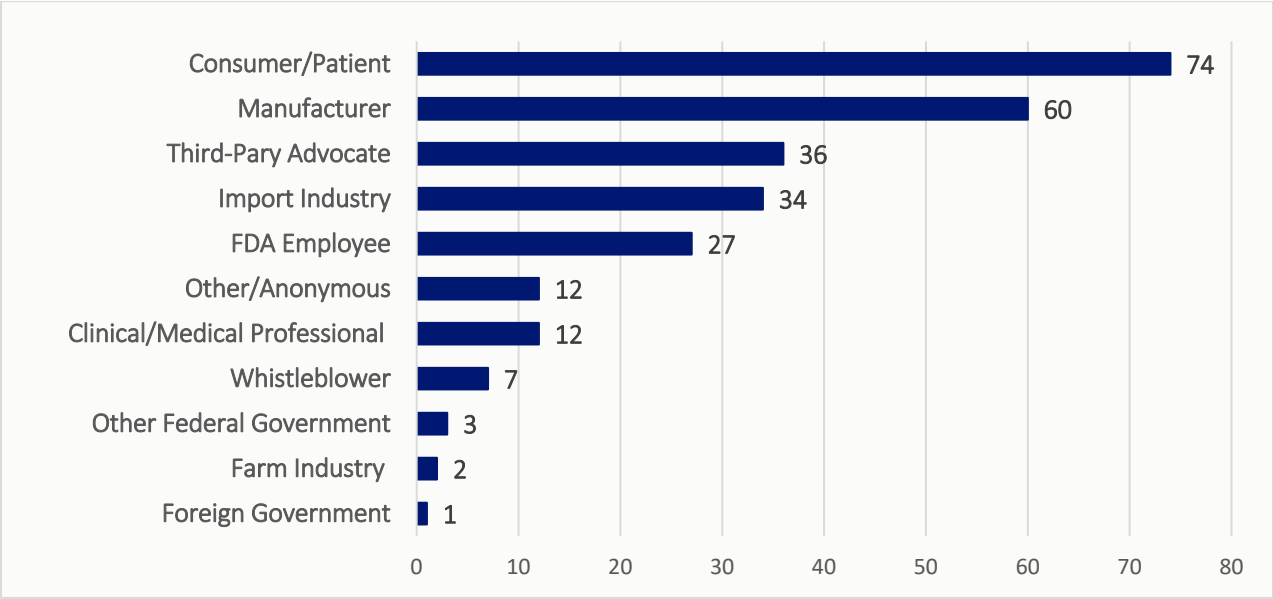
The distribution of inquiries by stakeholder category shown in **Figure 1** was developed from information provided by the inquirer. An individual or business entity requesting assistance from the ombudsman is not required to provide any stakeholder category related information. The table below (**Table 1**) includes a matrix to define the distinct categories used and how certain stakeholder groups are defined.

Table 1. Stakeholder Categories: Definitions

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

OOP PRACTICE BY THE NUMBERS

Figure 1. Inquiries by Stakeholder Category



Defining the 2019 data by internal and external stakeholders highlights FDA employees comprise 12% of the 275 inquiries received by the OOP. Internal inquiries handled by the ombudsman involve assistance with disputes, requests for a neutral perspective, brainstorming options, or general questions or concerns related to an internal process. All internal inquiries involving a human resource matter are referred to the Ombudsman & Conflict Prevention and Resolution staff in the Office of Commissioner's Office of Operations or an external resource. The OOP does not engage any matter or concern related to human resource issues.

Inquiry Categories

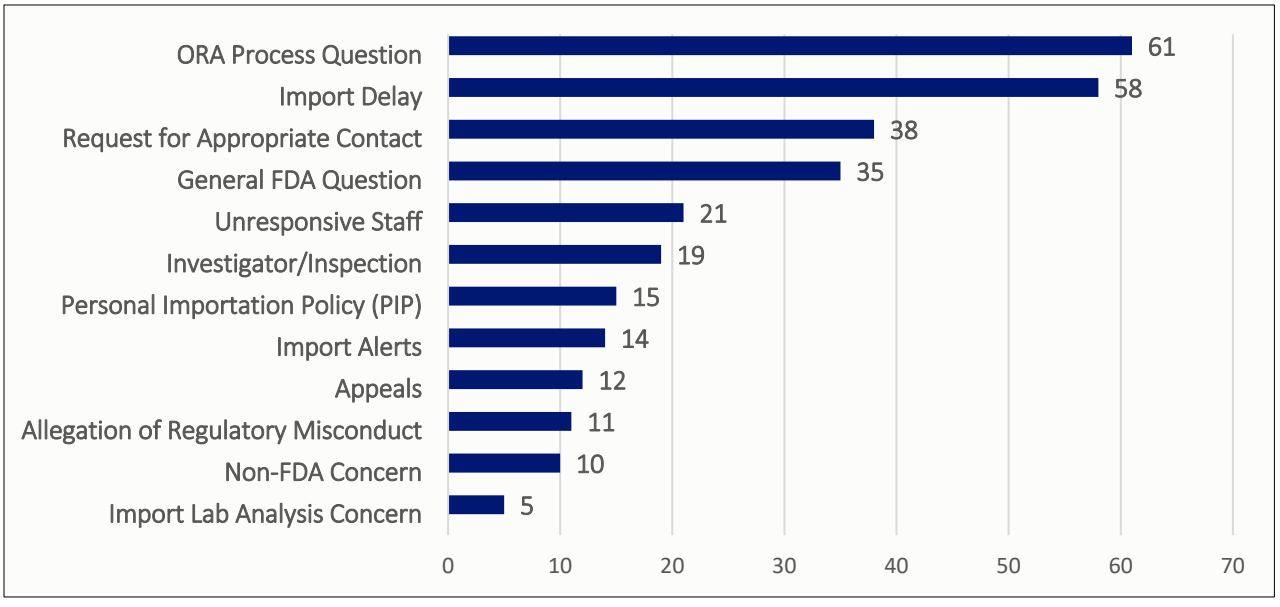
The most frequent recurring areas of concern identified within the 2019 inquiry data are arranged in descending order within **Figure 2**. The inquiry category areas of concern within this report were developed from data sorted and grouped directly from inquiries received in the 2019 calendar year. General questions about an ORA process matters are reported within the majority (198) of inquiries received by the OOP. To capture this category in a more significant way, the *ORA Process Question* category represents only those inquiries that indicated an *ORA Process Question* and no additional concerns. The *Allegations of Regulatory Misconduct* category includes reported allegations against firms in the regulated industry, individuals, and FDA employees. Other categories listed are explained by the descriptions within **Table 2**.

OOP PRACTICE BY THE NUMBERS

Table 2. Inquiry Categories: Definitions

Category	Definition
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
General FDA Question	Questions related to an FDA related product or process not ORA.
Unresponsive Staff	Problems contacting staff that has not responded after at least one documented attempt by the stakeholder
Investigator/Inspection	Question or concern related to an investigator or inspection
Personal Importation Policy (PIP)	Question or concern related to PIP
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.
Non-FDA Concern	Issue not related to FDA regulated product or process (referrals)
Import Lab Analysis	Question or concerns related to a lab result or sampling issue

Figure 2. Inquiry Categories (Most Common Areas of Concern)



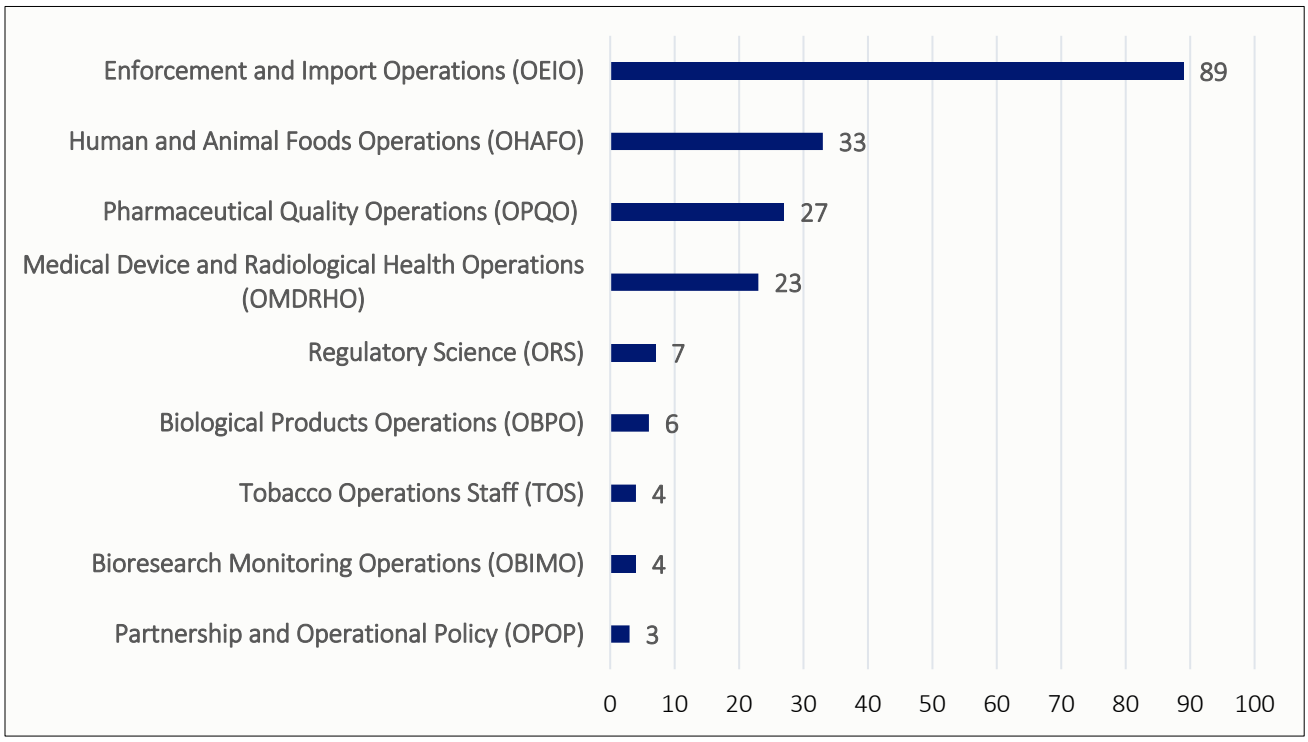
Apart from the *ORA Process Question* category, the numbers noted in **Figure 2** reflect the number of instances an issue or concern was reported. One inquiry may contain multiple issues or concerns, meaning one stakeholder may report multiple concerns in one interaction.

OOP PRACTICE BY THE NUMBERS

Analysis and Outcomes of OOP Inquiries

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. On an ongoing basis, the OOP keeps ORA management abreast of external stakeholders' concerns. Issues with common themes or trends are anonymized and reported to the Office of the ACRA for consideration of a systematic evaluation. To provide an understanding of how the inquiries received by OOP relate to ORA processes, **Figure 3** sorts the number of inquiries received in 2019 by the related ORA Program or Office.

Figure 3. Inquiry Numbers by ORA Program or Office



The ombudsman encourages all stakeholders to first attempt to resolve concerns or disputes with the division and if necessary, the Program Director of the Division or Office Director. If the issue is not resolved, that is the opportune time to contact the ombudsman. Every effort is made to respond to all inquiries in a timely and effective manner. An outcome that is facilitated in an equitable manner is the targeted result of an inquiry prior to closure. All inquiries are monitored until closure.

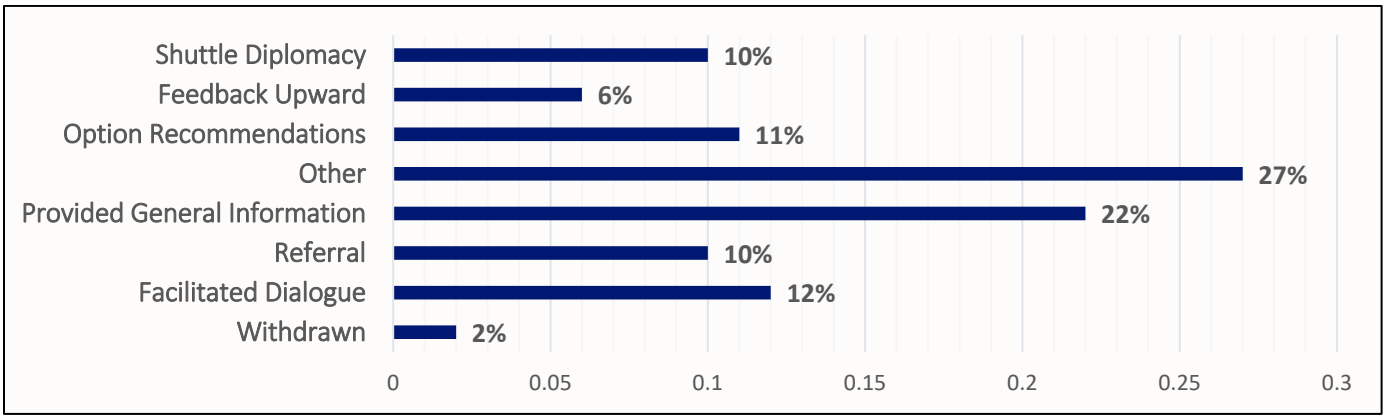
OOP PRACTICE BY THE NUMBERS

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. Common outcomes of closed inquiries are defined within **Table 3**. The data in **Figure 4** shows the related percentage of the defined common outcomes of inquiries closed in 2019.

Table 3. Outcome Category Definitions

Outcome	Definition
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.
Option Recommendations	Inquiry closed by providing education about administrative and policy options
Provided General Information	Inquiry closed by defining the steps for a specific ORA process.
Referral	Closed inquiry after referral to another ombudsman or other resource within ORA or FDA.
Facilitated Dialogue	Inquiry closed after facilitated discussions with stakeholder and ORA.
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 2019.

Figure 4. Common Inquiry Outcomes in 2019



Outreach Activities

Outreach activities, industry events, professional conferences, and professional development opportunities are planned before and during the calendar year. These activities are sought to increase awareness and elevate the visibility of the service provided by the OOP to internal and external stakeholders and to ensure the ombudsman maintains a thorough knowledge base of the ombudsman professional standards. The ombudsman presented information about the OOP to external stakeholder organizers in the medical device and drug industry in 2019. The ombudsman also presented information internally related to OOP and data recommendations from the 2018 annual report.

GOING FORWARD

OOP has established major goals that are underway for 2020 that include the following:

- **Expand education and understanding of the ORA Ombudsman Program**

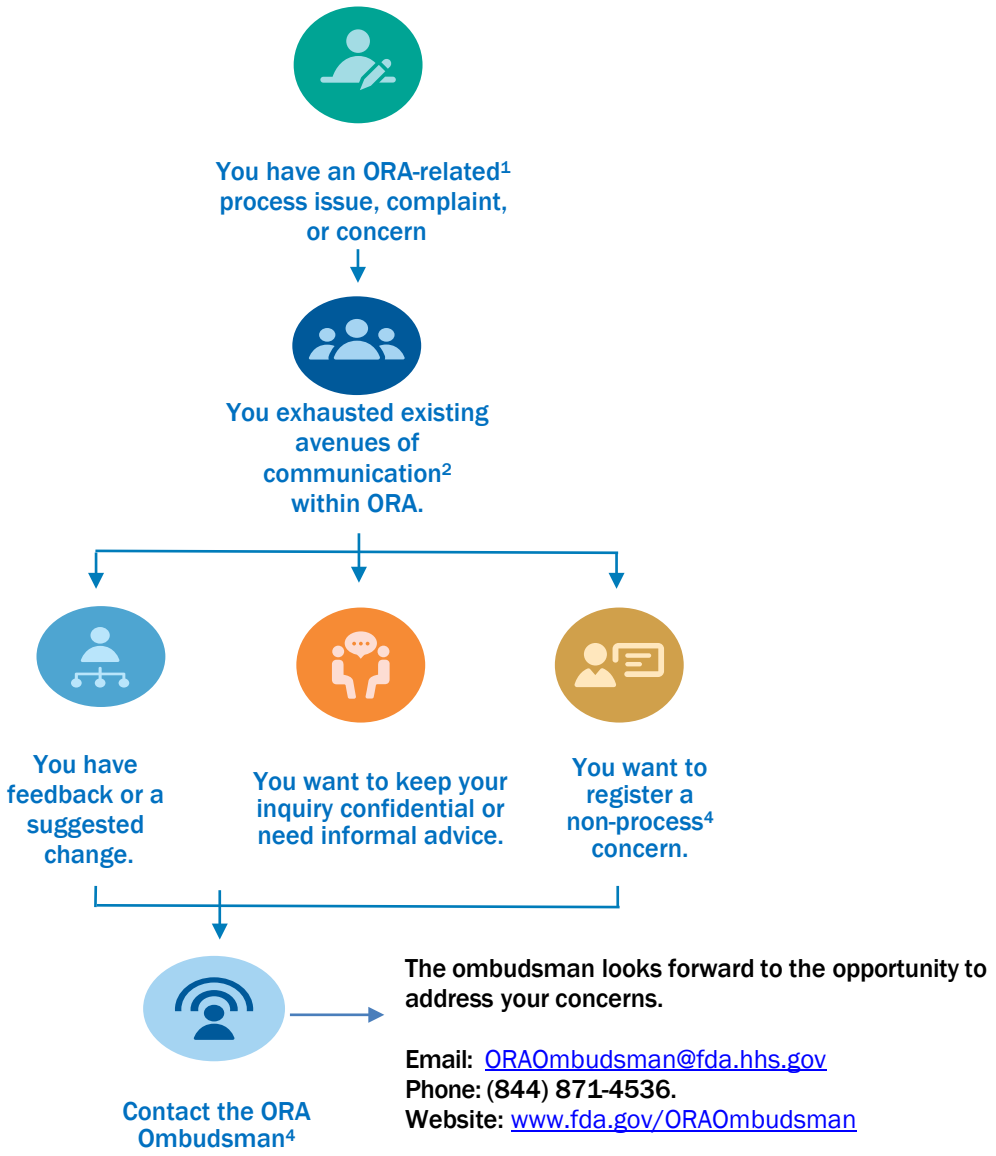
- **Continue to offer stakeholders a high, consistent level of service by demonstrating leadership in the ombudsman practice and profession.**

- **Capture and communicate individual and systematic process issues to ORA leadership and support resolutions by advocating for fair process solutions.**

Updates on the status of these goals will be included in the 2020 OOP annual report.

CONTACT THE OMBUDSMAN

When and How to Contact the Ombudsman



[1]ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States.
[2]FDA/ORA staff members and additional information about existing communication with ORA.
[3]Generally, a process concern will relate to steps taken or not taken to achieve an outcome or decision.
[4]The ombudsman cannot:

- Address internal human resource matters
- Delay enforcement or other regulatory actions or deadlines
- Serve as an advocate in any formal process
- Address matters in litigation