OFFICE OF REGULATORY AFFAIRS (ORA) OMBUDSMAN

CALENDAR YEAR **2018** / ANNUAL REPORT

ABOUT THE ORA OMBUDSMAN

ORA's Ombudsman is a neutral, impartial individual that informally resolves disputes and complaints while also serving as a one-stop-shop for advice or consultation for external stakeholders and FDA ORA staff.

The Ombudsman receives inquiries and investigates complaints in an informal, unbiased manner. The complaints and inquiries come 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 complaints or questions can be of a regulatory, scientific, or administrative nature. The Ombudsman helps these inquirers get to the right place within the agency to get their questions answered, informally assists in resolving disputes, and disseminates information about processes and other mechanisms for dispute resolution, both for disputes between regulated industry and ORA and for resolving differences of opinion among FDA staff. The actions taken by the Ombudsman are illustrated in Figure 1, below.

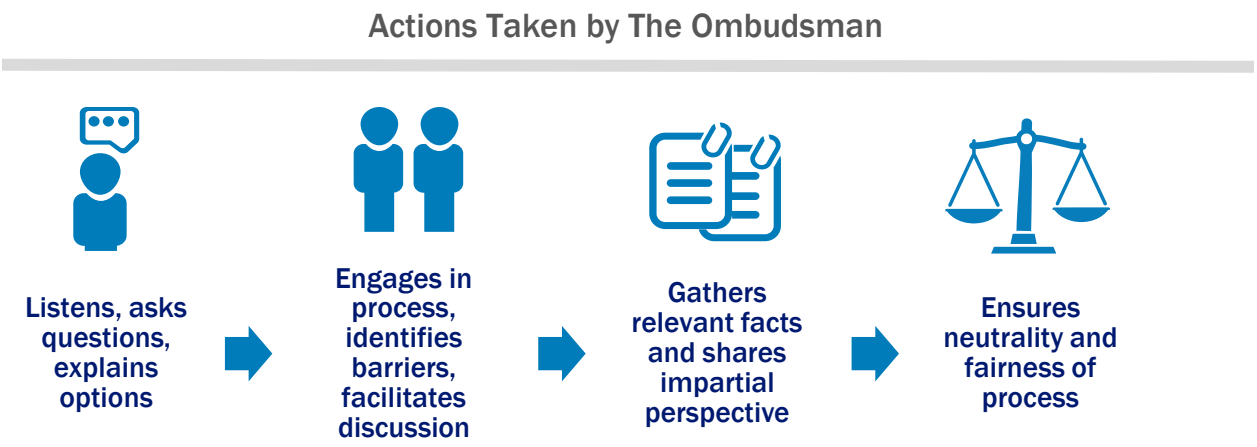

Figure 1. How the Ombudsman Handles Inquiries

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.

Core standards of the Ombudsman

Independence

Informality

Impartiality

Confidentiality
(when warranted)

WHO WE ARE

Jessica Zeller is the Ombudsman for the Office of Regulatory Affairs (ORA) and has held this position since its inception in 2015. She previously served in FDA's Office of the Chief Counsel and the Center for Tobacco Products. **Erica Katherine** is the Associate Ombudsman and has held this role since February 2019. Erica began her career at FDA in 2008 and brings extensive experience as a former investigator, compliance officer, and years of serving in multiple leadership roles within ORA.

Jessica Zeller / Erica Katherine

CALENDAR YEAR 2018

The Ombudsman received 272 inquiries from January 2018 to December 2018. An analysis of this data is as follows:

- The Ombudsman interacts relatively consistently with regulated industry (imports and domestic), individual consumers and third-party representatives, such as lawyers and consultants. See Figure 2, below:

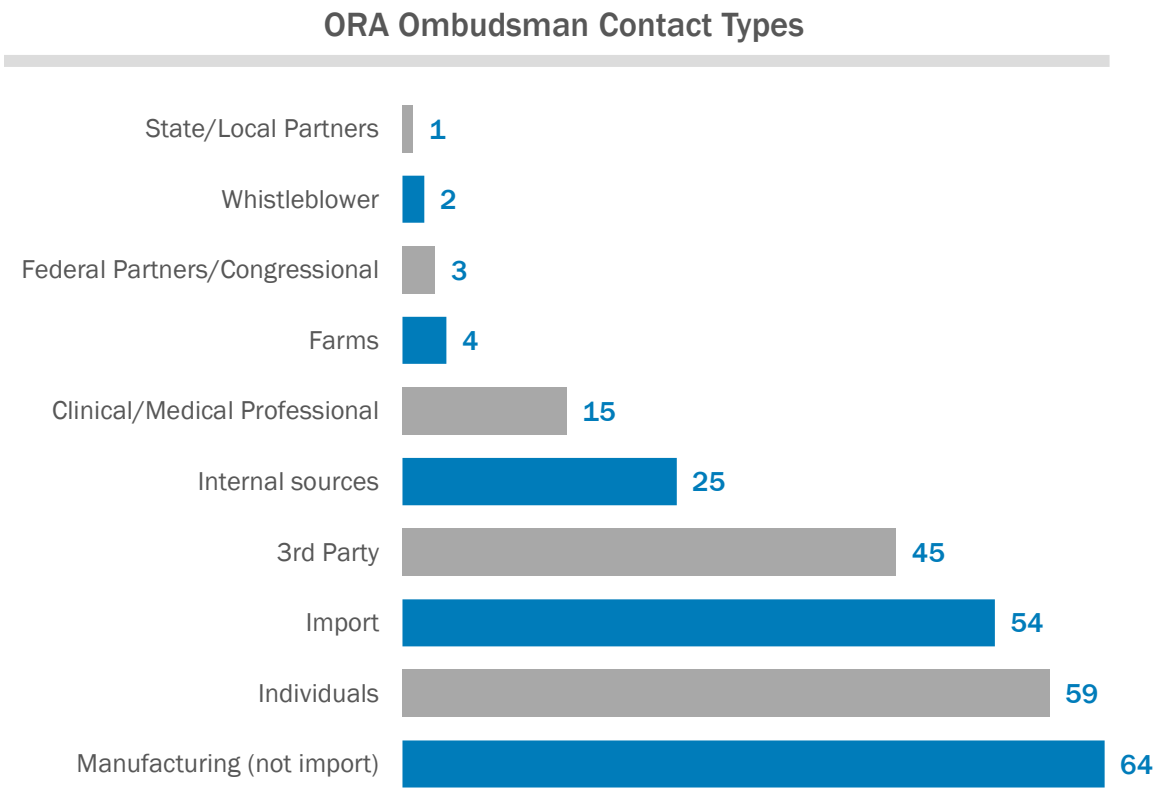

Figure 2. ORA Ombudsman Contact Types and Numbers in Calendar Year 2018

- The most common specific category of inquires involves imported products and/or operations. See Figure 3, below.

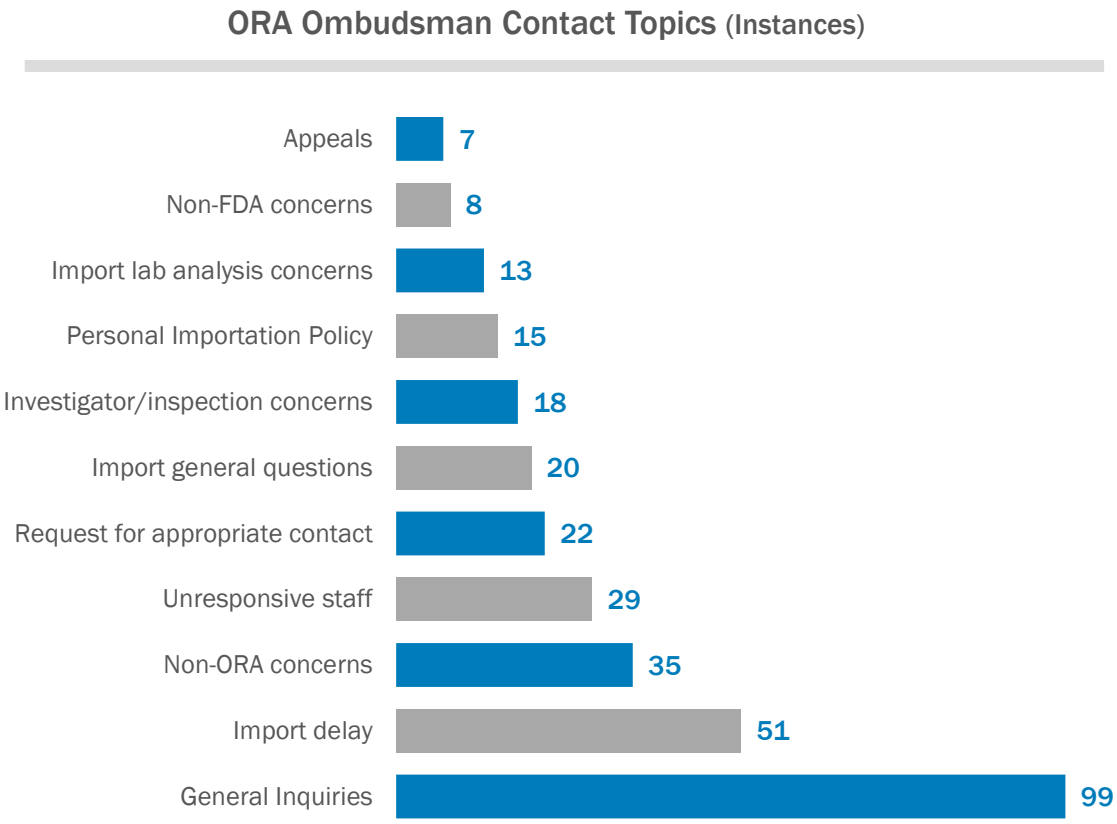

Figure 3. ORA Ombudsman Contact Topics and Numbers in Calendar Year 2018

- Inquirers ask about the full range of FDA-regulated products. See Figure 4, below.

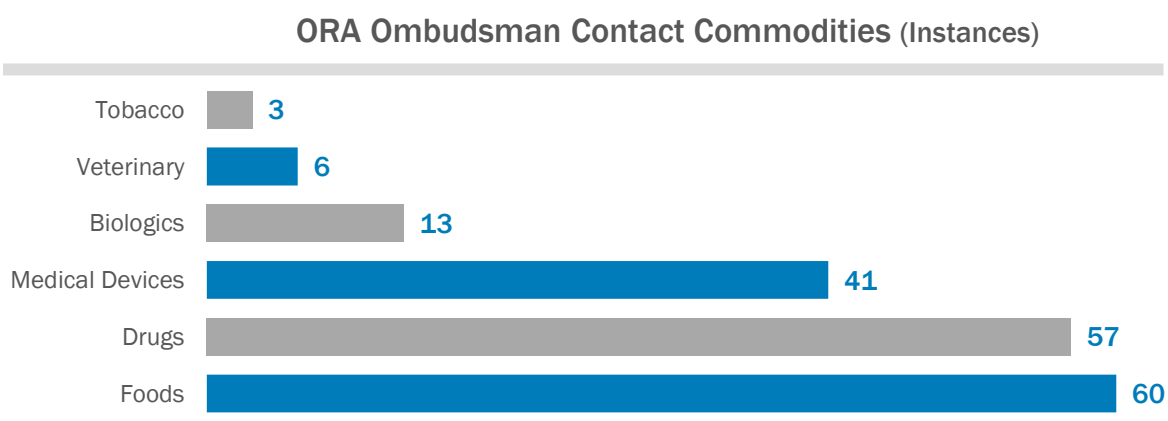

Figure 4. ORA Ombudsman Contact Commodities and Numbers for Calendar Year 2018

- In addition to external inquiries, the Ombudsman does a significant amount of work with internal facilitation as well

Our services were utilized more in 2018 than any year previously. The ORA Ombudsman has added a neutral perspective to internal policy discussions and provided feedback on complaint/dispute trends to assist in continuous improvement initiatives that assess compliance with agency and program objectives within ORA.

External and internal outreach, education, and engagement is a key focus for the Ombudsman and multiple forums were attended in 2018. The Ombudsman also continued to conduct external engagement with stakeholders to share information about our resources and to learn more about how those stakeholders engage with ORA.

1. 2018 External Outreach Forums

a. National Association of State Departments of Agriculture meeting with FDA regarding the Food Safety Modernization Act
b. FDA/Xavier PharmaLink Conference (pharmaceutical industry)
c. FDA/Xavier MedCon Conference (medical device industry)
d. Food and Drug Law Institute Enforcement Conference (cross program)

2. 2018 Internal Outreach Forums

a. Seattle District Office and Pacific Northwest Laboratory
b. West Coast Imports and International Mail Facility
c. Office of Chief Council presentation on ORA Program Alignment and Ombudsman
d. New York District Office, Division of Northeast Imports, and Northeast Medical Products Laboratory
e. Office of Pharmaceutical Quality Operations, Division 1, management face-to-face meeting
f. Denver District Office and Denver Laboratory
g. Quality Working Group presentation
h. Office of Biological Products Operations meeting
i. New England District Office and Winchester Engineering Analytical Center
j. Human and Animal Food East 4 all hands
k. Dallas District Office and Human and Animal Food West 3

WHEN & HOW TO CONTACT US

ORA Ombudsmen will assist any caller who may need help. However, we shouldn't always be your first call.

First, try your known contacts, or those listed on any notice you receive from the Agency – it works best if matters can be resolved directly at the lowest level necessary (See the contact chart below).

However, if that attempt is not working, give us a call. You can also call us if you have a process concern to share in confidence; are not sure where in the agency to obtain an answer; want to make the Ombudsman aware of an issue already shared with the agency that is not resolved or could be improved, or have a suggestion for broader process concern.

How to contact the ORA 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. See the following link for additional details: https://www.fda.gov/about-fda/office-global-regulatory-operations-and-policy/office-regulatory-affairs

[2]You find FDA/ORA staff members and find additional information about existing communication with ORA by assessing the following link: https://www.fda.gov/about-fda/office-regulatory-affairs/contact-ora

[3]Generally, a process concern will relate to steps taken or not taken to achieve an outcome or decision.

[4]**The ORA 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

For concerns not related to ORA, see the following for a listing of other Ombudsmen within FDA: https://www.fda.gov/about-fda/office-chief-scientist/contact-ombudsman-fda

If you feel that you could use the assistance of the ORA Ombudsman, please feel free to reach out directly to us.

Email: ORAOmbudsman@fda.hhs.gov

Toll-free 1-844-871-4536

Website: www.fda.gov/ORAOmbudsman

Jessica Zeller, ORA Ombudsman

Erica Katherine, ORA Associate Ombudsman