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

ANNUAL REPORT
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U.S. Food and Drug Administration
Office of Regulatory Affairs
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ORA OMBUDSMAN

2017 Annual Report

Overview

Jessica Zeller, J.D., is the ombudsman for the FDA's Office of Regulatory Affairs (ORA). Jessica Zeller reports to the associate commissioner for regulatory affairs (ACRA) who leads ORA. ORA's ombudsman position was created in 2015 to serve as an objective, neutral, confidential resource for stakeholders experiencing concerns with actions for which ORA was responsible.

I. Ombudsman's Role

The United States Ombudsman Association (USOA) defines a governmental ombudsman as "an independent, impartial public official with authority and responsibility to receive, investigate or informally address complaints about governmental actions, and, when appropriate, make findings and recommendations, and publish reports."

Simply put, the ORA ombudsman receives inquiries and investigates complaints in an informal, unbiased manner. Complaints and inquiries come from FDA-regulated industries, law firms, or consultants representing industry, advocacy groups, public and private research institutions, health care practitioners, consumers, and internal FDA sources. The complaints and inquiries can be of a regulatory, scientific, or administrative nature. The ombudsman informally resolves disputes and disseminates information about processes and other mechanisms for dispute resolution, both for disputes between FDA-regulated industries and ORA and for resolving differences of opinion among FDA staff.

The ombudsman follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombudsman (COFO), USOA, the International Ombudsman Association (IOA), and the Administrative Conference of the United States (ACUS) report "Recommendation 2016-5: The Use of Ombuds in Federal Agencies[1]." These include standards for ensuring confidentiality, impartiality/neutrality, and informality.

Ombudsman Vision: To enhance the FDA Office of Regulatory Affairs (ORA) operations by serving as a confidential resource to improve communication channels, resolve disputes, educate, and foster positive relationships with internal and external stakeholders.

II. Demographics and Most Common Topics

In 2017, the ORA ombudsman received communication regarding more than 250 separate matters, predominantly via email and telephone. In many instances, several phone calls and/or emails were exchanged per matter.

Many different stakeholders have used the resources of the ORA ombudsman's office. Those resources include:

Demographics (in relative order of frequency)

- Non-governmental stakeholders
  - Individual private citizens
  - Importer, broker, domestic/foreign manufacturer (import matter)
  - domestic/foreign manufacturer (non-import matter)
  - Law firms
  - Consultants
  - Consumer advocacy organizations
  - Clinical investigators
- Governmental stakeholders
  - ORA employees
  - Other FDA employees
  - State government officials
  - Foreign government officials

Most Common Topics (in relative order of frequency)

- Import matters
  1. Detentions, refusals, delays
  2. Personal importation
  3. Laboratory testing
- Administrative process inquiries
  1. Where to send an FDA Form 483 response
  2. Failure to receive an EIR under FMD 145
  3. Finding appropriate ORA contact information
  4. Advice related to approaching a dispute, including informal or formal appeal
- Lack of response from ORA office
- Interactions with district offices or ORA personnel
- Concerns about facility inspections (foreign and domestic)
- Concerns regarding regulation within an FDA Center, i.e. application review, approval questions, registration, etc.
- Whistleblower complaints
- Speaking/training requests

- ORA laboratory analytical findings and review
- Interactions with the Office of Criminal Investigations

III. Outreach

1. Produced and posted a short video[2] to explain the role of the ORA ombudsman
2. Produced and posted a frequently asked questions[3] to explain the role of the ORA ombudsman
3. As part of Program Alignment, presented to all six program management teams in the summer of 2017
4. Presented at three large industry meetings covering audiences for foods, medical devices, and drugs

IV. Feedback from Stakeholders

- "I wanted to formally thank you for setting up the meeting…it accomplished exactly what was needed."
- "Many thanks for your response and we appreciate your efforts. It is so nice to talk directly to an actual person."
- "Thanks for your response, I actually got a call from the [relevant office] today and this is now resolved. It was a pleasure working with you."

- "I know you have my best interests. I could feel it in our phone conversation."

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[1] https://www.acus.gov/recommendation/recommendation-2016-5-use-ombuds-federal-agencies
[2] https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm482210.htm
[3] https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm482210.htm