

# CTP Ombudsman's 2015 Annual Report



The Center for Tobacco Products (CTP) Ombudsman's Office responds to a range of contacts, including complaints from various stakeholders and the public, and facilitates the resolution of disputes between CTP and outside parties. While providing this service, the Ombudsman strives to maintain impartiality and neutrality.

Ella Yeargin is the Ombudsman for the Center for Tobacco Products. Ella has worked at CTP since 2011, and she arrived in the Ombudsman's Office in 2013. She started her federal career in CTP's Freedom of Information Act (FOIA) Office as a Presidential Management Fellow after graduating with a J.D. and certificate in public interest law from DePaul University College of Law. At DePaul, she focused on mediation, arbitration, restorative justice, and alternative dispute resolution within the criminal justice system. Before law school, Ella taught bilingual elementary education in The Bronx, NY.

In 2015, the Ombudsman's Office welcomed the Center's new Associate Ombudsman, Allison Monyei. Allison started her federal career in 2014 as a Regulatory Counsel in CTP's Office of Compliance and Enforcement. Prior to working at CTP, she worked as an attorney for 3 years with the National Veterans Legal Services Program, advocating on behalf of our nation's veterans and their families.

This annual report summarizes the role of the Ombudsman's Office and the complaints, disputes, inquiries, and comments the Ombudsman's Office received for calendar year 2015, including the number of contacts, their source, subject matter, and status.

## Ombudsman in Practice

### What is an Ombudsman?

An Ombudsman is an impartial, independent person who confidentially and informally receives and investigates complaints and facilitates the resolution of problems. CTP's Ombudsman's Office follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombudsman, the United States Ombudsman Association, and the International Ombudsman Association.

### What does the CTP Ombudsman's Office do?

The CTP Ombudsman's Office responds to inquiries and looks into complaints from all parties who contact us, including the tobacco industry, law firms or consultants representing industry, advocacy groups, public and private research institutions, health care providers, and consumers. We also facilitate the resolution of disputes between CTP and outside parties and provide general information on the regulatory process. While providing this assistance, the Ombudsman's Office maintains its independence, impartiality, and neutrality. The Ombudsman's Office is an advocate for fairness.

Serving as a primarily external Ombudsman's Office, we:

- Address complaints
- Help resolve disputes of a scientific, regulatory, or procedural nature
- Discuss appeal and dispute resolution options
- Respond to inquiries

This annual report summarizes the role of the Ombudsman's Office and the contacts received during calendar year 2015, including the number of contacts and their source, subject matter, and status. This report also provides some trends in the number and type of contacts over the past 5 years.

We do not  
advocate for one  
side or the other,  
but we do advocate  
for a fair process.

The Ombudsman's Office is available to listen to issues and concerns even if they do not rise to the level of a complaint or dispute. The Ombudsman's Office can also help to facilitate a dialogue or discussion between external parties and CTP staff.

Based on the nature of the contacts received from the public, the Ombudsman advises the Office of the Center Director, where the Ombudsman's Office is located, on ways to assure that CTP's procedures, policies, and decisions are fair and equitable.

The Ombudsman is also an internal Ombudsman who plays a role in the resolution of internal scientific disputes in regulatory decision-making between CTP managers and staff.

### **Why should someone contact the Ombudsman?**

The Ombudsman's Office provides a "safe space" for external parties to voice their questions, concerns, or complaints about CTP and its regulation of tobacco products. We work to help members of the public, tobacco companies and their representatives, public health advocates, and any other person from outside of CTP who contacts us. Using our deep understanding of Center operations and interacting with FDA staff, we can improve communications and working relationships while also helping to de-escalate conflicts between CTP and outside parties. Because we are confidential, impartial, independent, and informal, we can listen, assess difficult situations, identify options, and ultimately resolve issues at an early stage.

### **Confidentiality**

If you contact the Ombudsman's Office, you may want to keep your name, company or organization name, or even the reason for your complaint confidential. Generally, we can keep this information confidential if you ask. However, keeping this information confidential might make it difficult for us to help you with a specific problem. If that happens, we'll let you know and won't keep looking into your problem without your permission to share the information about you and the specifics of your case.

However, there are a few areas where we can't keep your information confidential. The first one is if you make a threat against yourself or another person. Another is if we're required to share your information by law. However, you should know that FDA has a very strict non-retaliation policy that protects anyone who complains about the Agency or any of its employees.

### **Impartiality**

We do not advocate for one side or the other, but we do advocate for a fair process. No one in the Ombudsman's Office may hold any office or position that would compromise his or her ability to be impartial.

### **Independence**

We are outside of the business chain of command. The Ombudsman reports to the CTP Deputy Director and has direct access to the CTP Director.

### **Informality**

We're here to help. It's important for us to understand what the issue is, hear what solution you're hoping for, and to figure out what can be done to help. We encourage you to raise all issues to your CTP point of contact (e.g., CTP's Office of Small Business Assistance or a company's designated Regulatory Health Project Manager) before reaching out to the Ombudsman's Office, but you can email or call anytime. No formal memo or letter is needed, and, in fact, we can't serve as formal notice to the Agency.

### **When to Contact Us**

The CTP Ombudsman's Office can help you by:

- Answering general questions on CTP's regulatory process
- Discussing possible ways to help you resolve a problem with CTP
- Contacting individuals within CTP on your behalf



- Connecting you with someone who can assist you
- Encouraging effective communication between CTP and outside entities
- Acting as a source of early detection for emerging system-wide issues
- Answering questions about CTP’s regulation of tobacco products or looking into complaints from CTP’s regulated industry, law firms or consultants representing tobacco companies, advocacy groups, public and private research institutions, health care providers, and consumers
- Facilitating the resolution of disputes between CTP and outside parties
- Identifying options you have to appeal a CTP decision

The Ombudsman’s Office can provide an empathetic ear for issues and concerns even if they do not rise to the level of a complaint or dispute.

### What to Expect From Us

The Ombudsman’s Office will listen carefully to your complaint, ask questions (including about your desired outcome), and review your options for moving forward. This process may be very quick and take only a few minutes, or we might need to take some time to look into the issue. Again, we will keep what you tell us confidential unless we have serious concerns about your or someone else’s safety or unless disclosure is required by law.

Depending on the situation, we may:

- Seek additional information from CTP employees or offices that know about your case
- Point you in the direction of applicable laws, regulations, policies, and data
- Participate in meetings to support effective communication and problem-solving
- Facilitate conversations between you and CTP
- Refer you to someone else, either within CTP or elsewhere

The Ombudsman’s Office does its best to respond in a timely and effective manner. Although anyone may contact our office at any time, people should first try, if possible, to resolve any complaint or dispute within the responsible CTP Office. The Ombudsman’s Office cannot get involved in matters that are in active litigation.

## Contact Trends

The CTP Ombudsman receives inquiries, complaints, and contacts about disputes by phone, postal mail, email, and in person.

The Ombudsman’s Office cannot get involved in matters that are in active litigation.

## Inquiries, Complaints, and Disputes



### Inquiry

An inquiry may be about an issue that does not rise to the level of a complaint or a dispute, such as an inquiry about the regulatory process.

### Complaint

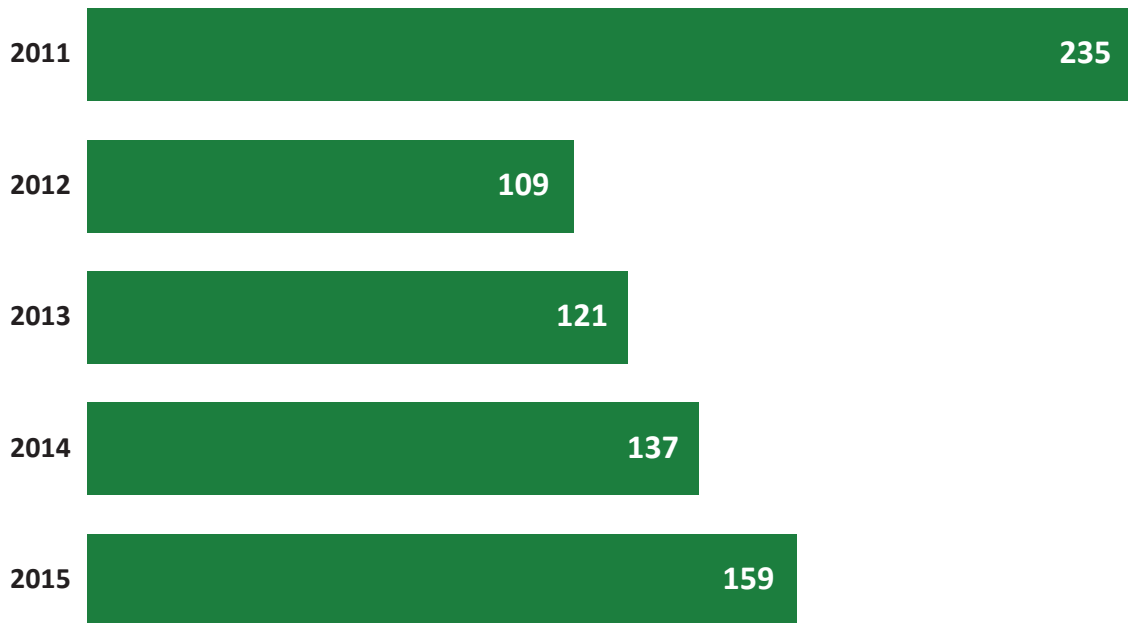
A complaint might be an expression of dissatisfaction with a CTP policy or action. It might be a trade complaint about a tobacco company or retailer, or a consumer complaint about a product or type of product.

### Dispute

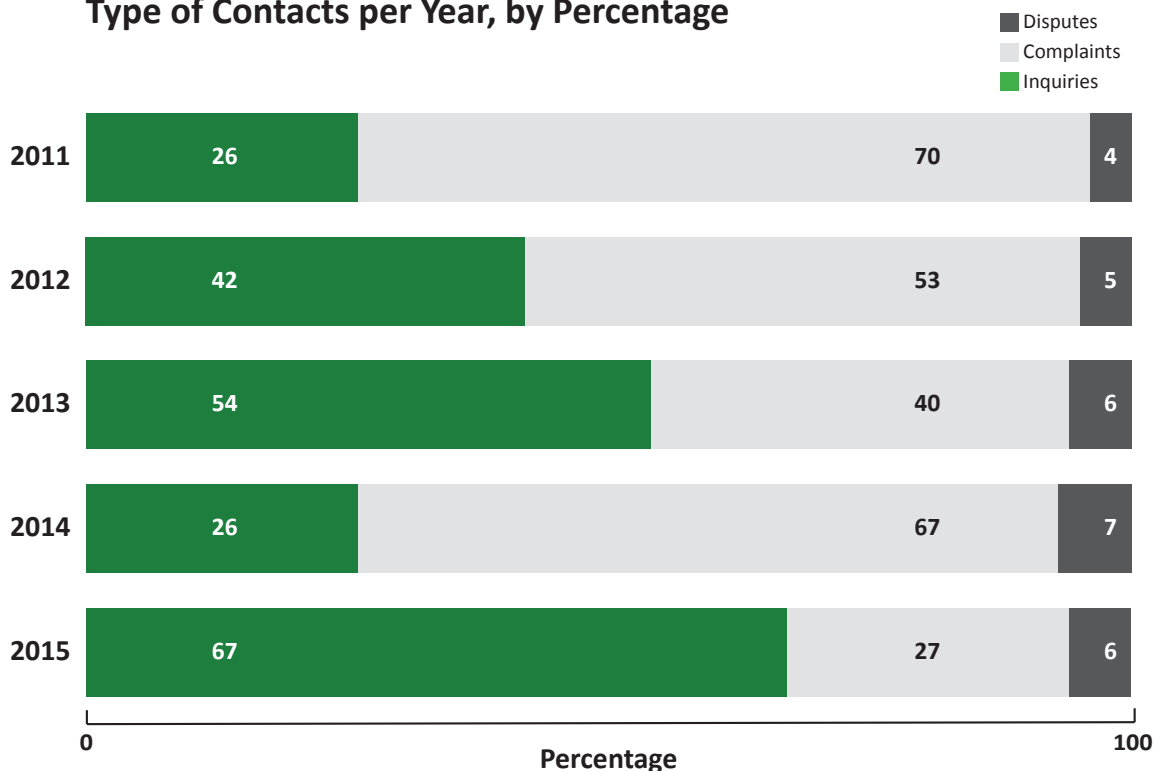
A dispute may involve a disagreement with, a challenge to, or an appeal of a CTP decision or action.

The CTP Ombudsman’s Office was created in 2010. Over the past 5 years, there have been trends in the number and type of contacts to the Office. In 2011 and 2014, there were increases in the number of complaints compared to the previous year. These were also the years when the CTP Ombudsman's Office was first established and when CTP issued the proposed deeming rule, which would extend CTP's jurisdiction to include all tobacco-derived products, respectively.

### Number of Contacts per Year



### Type of Contacts per Year, by Percentage

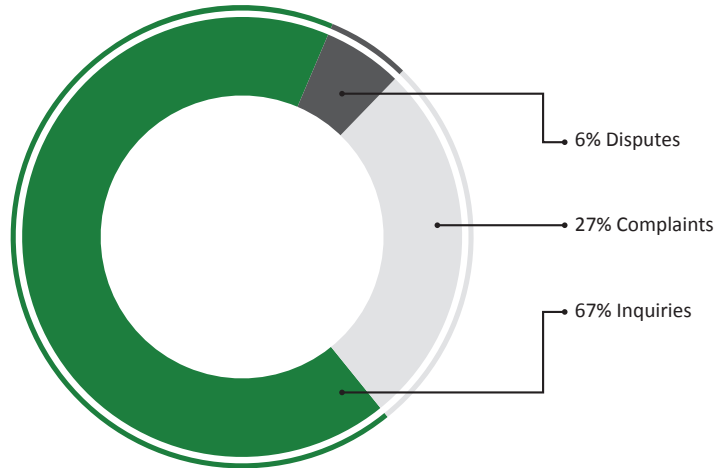


# Contacts in 2015

In 2015, the CTP Ombudsman received communications from 159 contacts, an increase from the 137 received in 2014. In many instances, several phone calls or emails are exchanged with a single contact; however, these follow-up correspondences are counted as a single interaction for purposes of the annual report unless substantially different issues were raised.

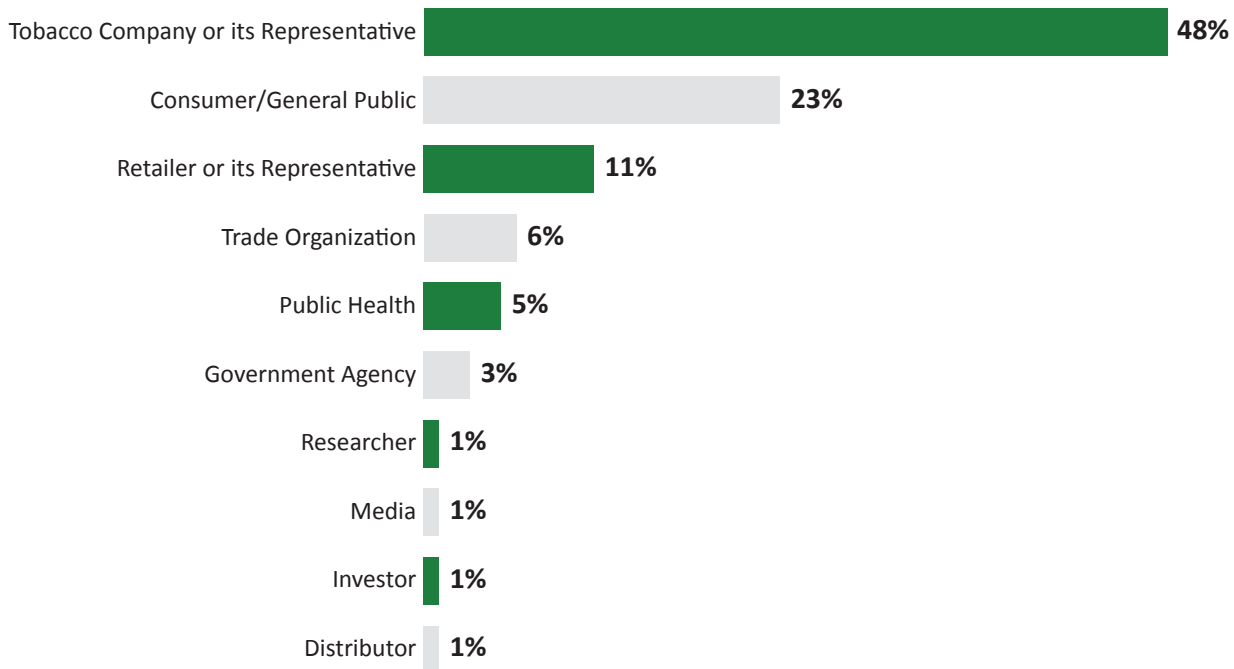
## Contacts Received in 2015

Total: 159



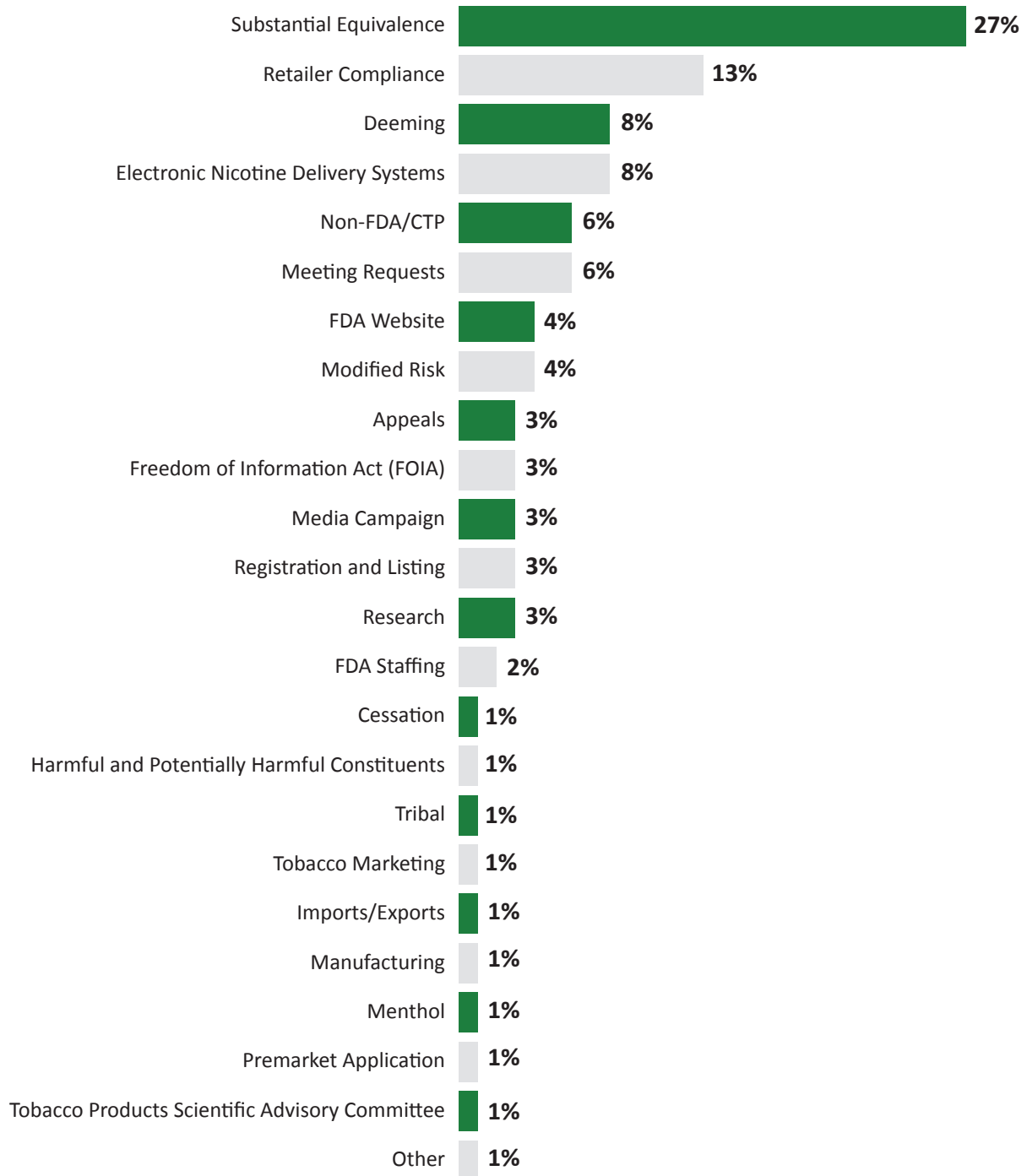
Ninety-seven percent of contacts received in 2015 were closed. This means that the complaint was addressed, the dispute or appeal was resolved, or the inquiry was responded to, referred outside CTP, withdrawn, or had no follow-up by the initiator after 3 months. This includes contacts carried over from 2015 and closed in 2016.

## Source of Contacts



## Subject Matter

(Total more than 100% due to rounding)



We will keep what you tell us confidential unless we have serious concerns about your or someone else's safety or unless disclosure is required by law.

In 2015, as in years past, the subject matter of the contacts reflects a high level of interest in and engagement with CTP from outside of FDA.

This year, more tobacco companies and their representatives reached out to the Ombudsman's Office, resulting in an increase from years past. Contacts had questions, comments, and concerns about electronic nicotine delivery systems and the proposed deeming rule, retailer compliance and inspections, and substantial equivalence. In 2015, complaints and inquiries related to substantial equivalence included concerns about timeliness and communication and requests for assistance with extension and meeting requests, while members of the public typically wrote and called with questions and opinions about the proposed deeming rule and e-cigarettes.

## Appeals

The CTP Ombudsman's Office coordinates the resolution of conflicts pursuant to 21 CFR 10.75 for the Center. Under Section 10.75, "an interested party outside the agency may request supervisory review of a decision through the established channels of supervision or review."

In 2015, CTP processed four appeals, all at the Center level (e.g., a party appealed a decision of one of the five Offices within CTP). As of December 31, 2015, one appeal received a final decision, and three remained under review. For more information about how to submit an appeal pursuant to Section 10.75, please contact the Ombudsman.

## Summary

In 2015, a wide variety of individuals, companies, and trade associations with complaints or disputes with CTP's regulatory authorities and processes contacted the Ombudsman's Office for assistance. Additionally, a record number of consumers, retailers, manufacturers, public health officials, representatives from the tobacco industry, and more reached out to ask questions: When would CTP issue its final deeming rule? How can someone request a meeting with a CTP Office or official? Would CTP grant additional time to respond to a regulatory letter? What were the next steps a retailer should take to respond to a warning letter?

Also in 2015, the Ombudsman's Office broadened its outreach efforts. This included attending and, where invited, presenting at events including trade shows, industry conferences, trade association meetings, and public workshops hosted by CTP. Ella Yeargin also continued to present to CTP new employees, filmed and published the first CTP Ombudsman webinar, and updated the CTP Ombudsman Internet site.

The coming year promises to be an exciting one for CTP, and we look forward to broadening our engagement with all interested parties. If you have a question or a concern that you would like to discuss with the CTP Ombudsman, please do not hesitate to contact us at 301.796.3095.



# CTP Ombudsman at a Glance

## Why is there a CTP Ombudsman?

The Center for Tobacco Products (CTP) Ombudsman's Office is responsible for responding to a range of contacts, including complaints from various stakeholders and the public, and facilitating the resolution of disputes between CTP and outside parties.

## Confidentiality

We will keep what you tell us confidential unless we have serious concerns about your or someone else's safety or unless disclosure is required by law.

## Impartiality

We do not advocate for one side or the other, but we do advocate for a fair process.

## Independence

We are outside of the business chain of command. The Ombudsman reports to the CTP Deputy Director and has direct access to the Director.

## Informality

We are here to help. It is important for us to understand what the issue is, to hear what solution you are hoping for, and to figure out what we can do to help.

## Why should I contact the CTP Ombudsman?

We can assist in informally resolving issues by facilitating discussions, brainstorming and evaluating options and resources, offering an impartial perspective, ensuring confidentiality of someone's identity, engaging in shuttle diplomacy, and providing recommendations, among other options.

## When should I contact the CTP Ombudsman?

Try us when you have not had success with existing CTP processes to address your concerns or because you want to keep your concerns confidential. You are welcome to call or email us any time, but we encourage you to work with your existing CTP contact first.

Last Updated April 2016  
CTP-63

## Ombudsman's Office

301.796.3095

[CTPOmbudsman@FDA.hhs.gov](mailto:CTPOmbudsman@FDA.hhs.gov)

<http://www.fda.gov/TobaccoProducts/AboutCTP/>

[ContactUs/ucm2023130.htm](http://www.fda.gov/TobaccoProducts/AboutCTP/ContactUs/ucm2023130.htm)

