



# CTP OMBUDSMAN'S 2016 ANNUAL REPORT

The Center for Tobacco Products (CTP) Ombudsman's Office responds to a wide 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 confidentiality.

In 2016, the Center welcomed Nathan Hurley as its acting ombudsman, replacing previous Ombudsman Ella Yeargin. Nathan has worked at CTP since 2010 and began a detail to the Ombudsman's Office in November 2016. He started his federal career as a park ranger in the National Park Service after graduating from Shepherd University with a bachelor's degree in environmental science. Nathan came to CTP's Office of Science in 2010 as a staff assistant and worked his way up to lead regulatory health project manager. During his more than 6 years of experience in CTP, Nathan has helped to develop and shape the Center's processes and procedures. Nathan joins Associate Ombudsman Allison Monyei in the Ombudsman's Office.

This annual report summarizes the role of the Ombudsman's Office and the complaints, disputes, inquiries, and comments the office received during calendar year 2016, including the number of contacts and their source, subject matter, and status.

## OMBUDSMAN IN PRACTICE

### **What is an ombudsman?**

An ombudsman is an impartial, independent person who confidentially receives and investigates complaints and facilitates the resolution of problems. The Ombudsman's Office within CTP 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 external parties and provide general information on the regulatory process. While providing this assistance, the Ombudsman's Office maintains its independence and impartiality. The Ombudsman's Office is an advocate for fairness.

*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.*

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 also can help to facilitate a dialogue or discussion between outside parties and CTP offices and 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 CTP’s procedures, policies and decisions are of the highest quality and are fair and equitable.

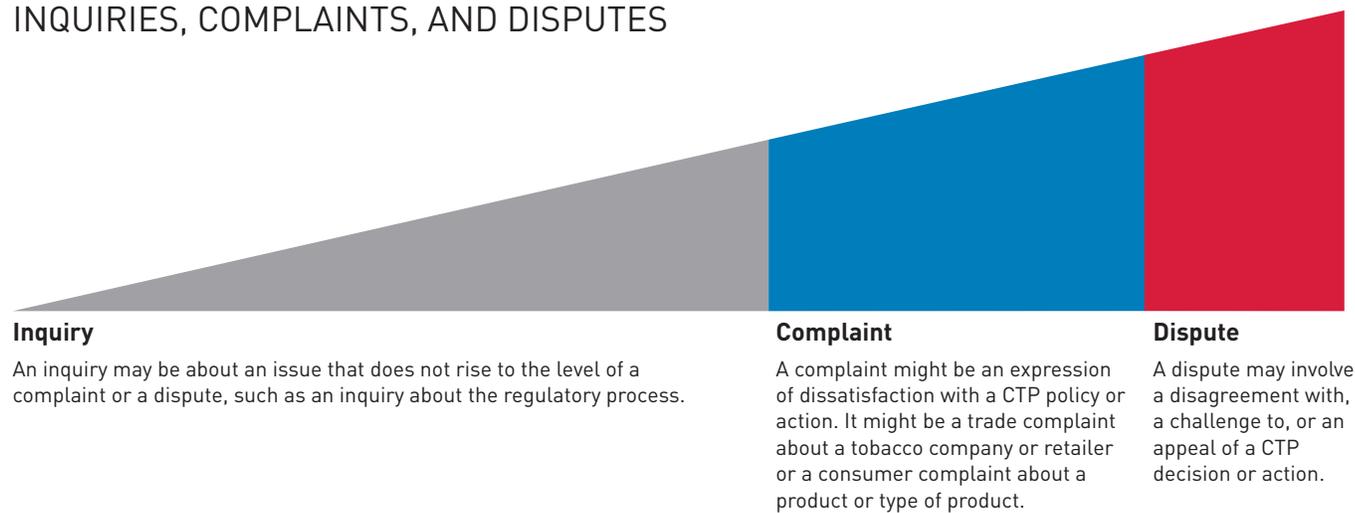
The CTP Ombudsman is also an internal ombudsman who plays a role in the resolution of internal scientific disputes in regulatory decision making between CTP managers and staff.

*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.*

## CONTACT TRENDS

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

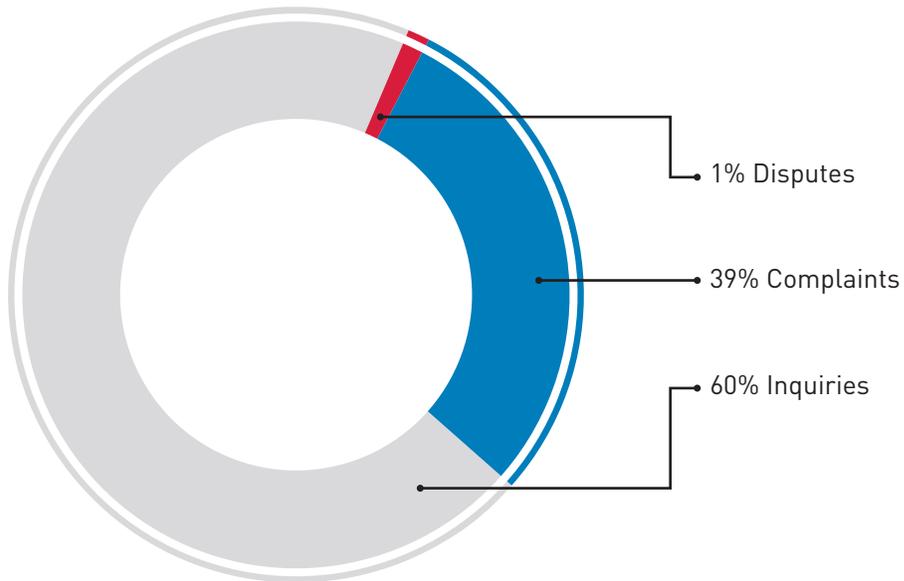
### INQUIRIES, COMPLAINTS, AND DISPUTES



In 2016, the CTP Ombudsman’s Office received 320 contacts, a significant increase from the 159 received in 2015. In many instances, several phone calls or emails were exchanged with a single contact; however, these follow-up correspondences are counted as a single interaction for the purposes of this annual report unless substantially different issues were raised. This is the highest number of contacts the Ombudsman’s Office has experienced since its creation in 2010.

## CONTACTS RECEIVED IN 2016

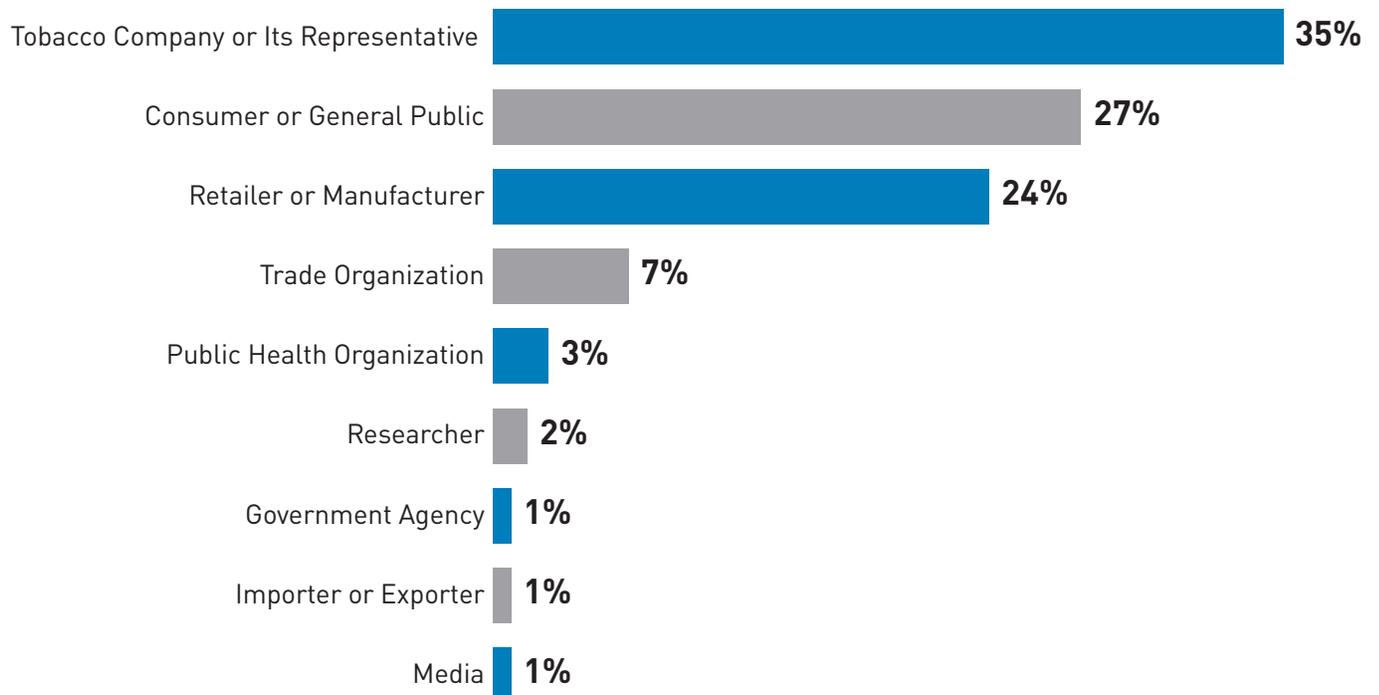
TOTAL: 320



Ninety-eight percent of contacts received in 2016 were closed. This means 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 1 month. This includes those contacts carried over from 2016 and closed in 2017.

## SOURCE OF CONTACTS

(Total is more than 100% due to rounding)



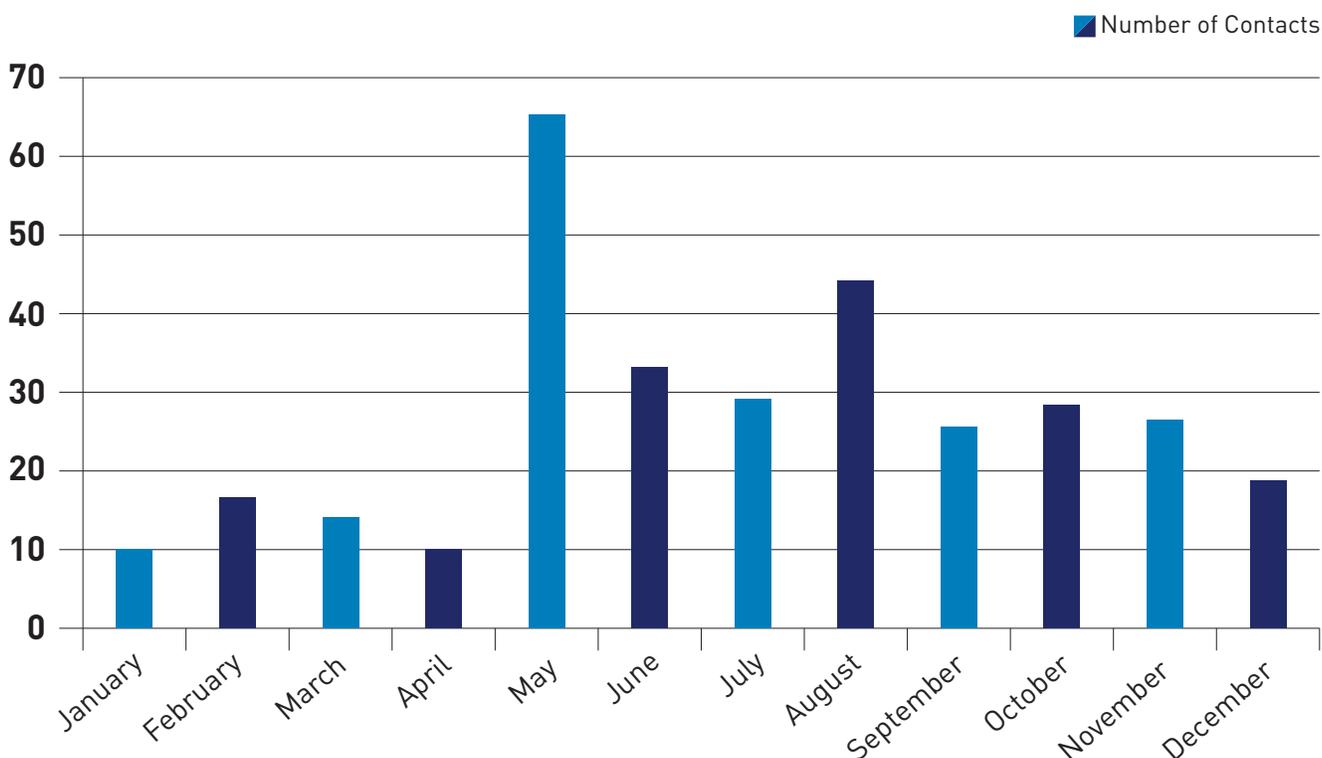
As in 2015, tobacco companies and their representatives reached out to the CTP Ombudsman’s Office more than other sources in 2016. There was a higher percentage of complaints in 2016 than in 2015. Contacts from retailers and manufacturers also increased, mainly due to the publication of the final deeming rule in May.

This rule extends FDA’s regulatory authority to all tobacco products, including e-cigarettes and all other electronic nicotine delivery systems (ENDS), cigars, hookah tobacco (also called waterpipe tobacco), pipe tobacco, nicotine gels, and dissolvables that did not previously fall under FDA’s authority.

### The Impact of Publishing the Final Deeming Rule

Publication of the deeming rule in May 2016 brought a significant increase in contacts to the Ombudsman’s Office. In 2016, 181 visitors contacted our office about the deeming rule or about newly regulated tobacco products. The following chart shows periods of increased interaction with the Ombudsman’s Office, primarily in May and August. These months coincide with the publication and the effective date of the deeming rule, respectively.

## DEEMING-RELATED CONTACTS BY MONTH

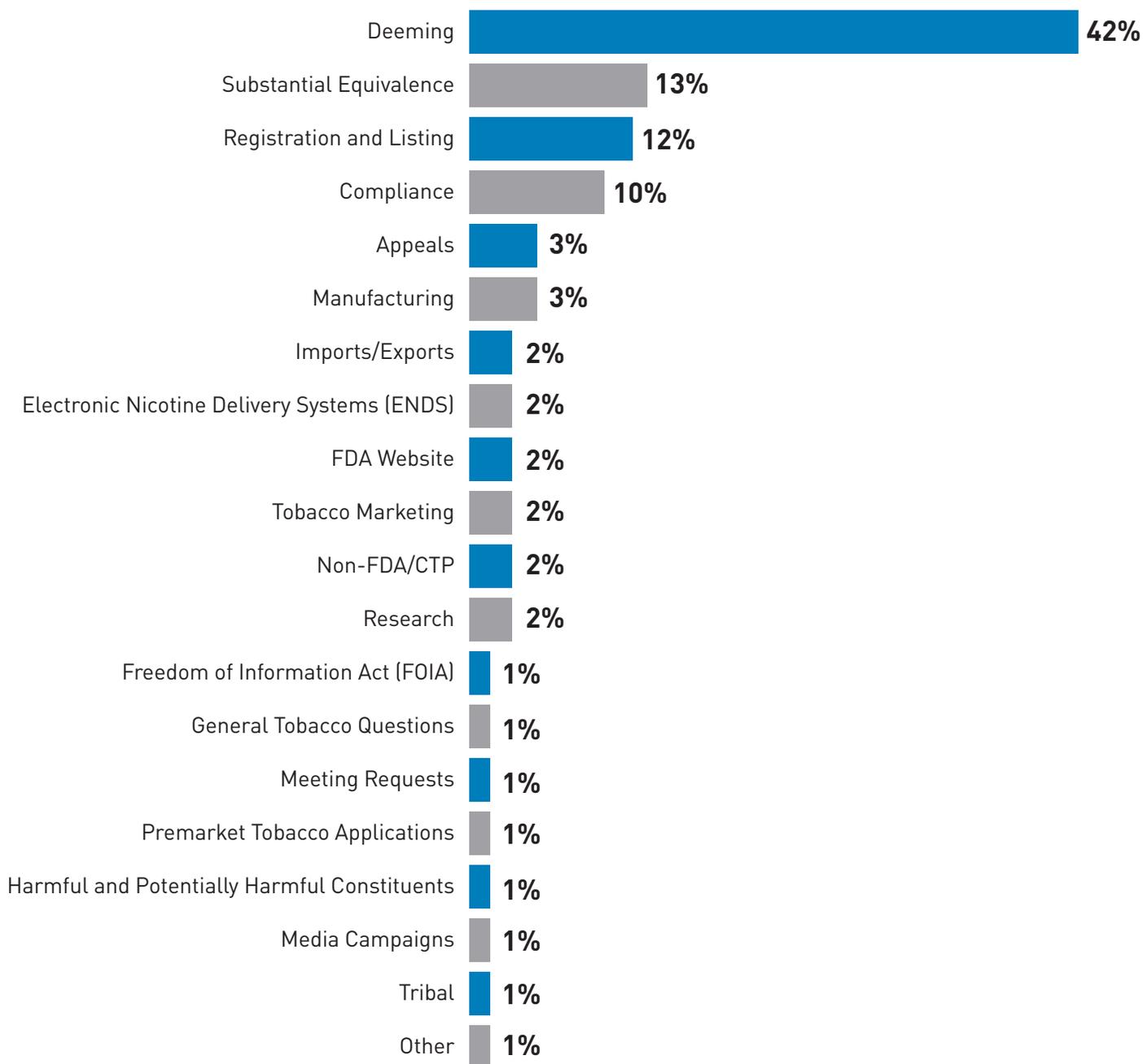


### A Snapshot of the First Days after Publishing the Deeming Final Rule

The Ombudsman’s Office received its first deeming-related contacts on the day of the announcement, May 5, 2016. The majority of initial contacts came from consumers, who wanted to share stories of e-cigarette use and vaping. Many consumers expressed frustration about the deeming rule’s effects and were concerned about their future ability to continue using vape products as a substitute for cigarettes. Others wanted clarity about what FDA considers a tobacco product. Ten days after publication, the contact profile changed from consumers to retailers and manufacturers who were looking for information about the deeming rule’s effect on small businesses and how to comply.

## CONTACT TOPIC OF INTEREST

(Total is more than 100% due to rounding)



In 2016, the contact topics of interest reflected a high level of engagement with CTP from parties outside of FDA. As mentioned above, the deeming rule, its application to newly regulated industry, and its effect on consumers were the primary topics of interest this year. And, as in years past, contacts still had questions, comments, and concerns about the substantial equivalence product review pathway and complying with requirements to register manufacturing establishments and list tobacco products.

Complaints and inquiries related to the substantial equivalence product review pathway included concerns about communication with CTP and the overall timeliness of the application process. Registration and listing complaints and inquiries increased this year as this requirement was one of the first compliance activities newly regulated industry would need to perform.

## FORMAL DISPUTE RESOLUTION

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

In 2016, CTP issued decisions on three appeals and refused to accept one appeal request. For more information about how to submit an appeal pursuant to 10.75, please contact the ombudsman.

## SUMMARY

In 2016, a wide variety of individuals, companies, and trade associations with questions, 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 others reached out to share concerns: Why has CTP decided to regulate e-cigarettes? How can someone request a meeting with a CTP office or official? Would CTP grant additional time to respond to a regulatory letter? How should a newly regulated manufacturer submit product listings and register a facility?

Also in 2016, the Ombudsman's Office continued its outreach efforts. This included attending and presenting at events including industry conferences, trade association meetings, and public workshops hosted by CTP. The ombudsman and the associate ombudsman continued to meet and interact with CTP new employees and to update the CTP Ombudsman website.

In the coming year, we look forward to broadening our engagement with all interested parties. If you have a question or a concern you would like to discuss with the CTP ombudsman, please do not hesitate to contact us at 301.796.3095.

# CTP OMBUDSMAN'S OFFICE 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.

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## 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.

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## IMPARTIALITY

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

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## 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.

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## 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.

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**Why should I contact the CTP ombudsman?** We can help resolve 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.

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**CENTER FOR TOBACCO PRODUCTS**  
OMBUDSMAN'S OFFICE

301.796.3095

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

<https://www.fda.gov/tobaccoproducts/aboutctp/contactus/ucm2023130.htm>



Last Updated March 2017  
CTP-94