CTP OMBUDSMAN'S REPORT *2024*

CENTER FOR TOBACCO PRODUCTS

U.S. FOOD & DRUG ADMINISTRATION

CTP OMBUDSMAN MESSAGE

We are pleased to present the U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) Ombudsman (Ombuds) annual report for the calendar year 2024. The Ombuds' goal is to provide a process to investigate and settle disputes, resolve complaints, ask clarifying questions, determine desired outcomes, discuss options forward, and facilitate external and internal stakeholder communication.

The CTP Ombudsman Team serves as a confidential, impartial, independent, and informal resource that assists external and internal stakeholders.

Externally, the CTP Ombuds answers inquiries, acknowledges complaints about CTP's regulatory process, redirects contacts to the appropriate office, discusses dispute resolution options, and serves as a neutral resource to stakeholders. Internally, the Ombuds works toward CTP's mission and goals, helps develop guidance, facilitates the scientific dispute resolution process internal to CTP, and provides FDA staff with informal advice.

The Ombuds acts as a source of early detection for emerging system-wide issues and works with the center on ways to assure that CTP's procedures, policies, and decisions are fair.

The CTP Ombuds follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombuds, the United States Ombudsman Association, and the International Ombuds Association:

Confidentiality

We will keep what you tell us confidential unless we have serious safety concerns or disclosure is required by law.

Impartiality

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

Independence

We are outside of the business chain of command. We report to the CTP Deputy Director and have direct access to the CTP Director.

Informality

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

We welcome any feedback you may have on this report to help us improve our services and better meet the needs of our stakeholders.

Contact the CTP Ombuds for assistance or more information:

301.796.3095

CTPOmbudsman@fda.hhs.gov

www.fda.gov/tobacco-products/contact-ctp/ctp-ombudsman

This report summarizes the CTP Ombuds' role in addressing the inquiries, complaints, and disputes received for the calendar year 2024, including the number of contacts, contact stakeholders, and topics of interest.

2024 CONTACT TRENDS

274 Number of contacts CTP Ombuds addressed

Note: Total is more than 100% due to rounding.

A contact addressed is any interaction between the CTP Ombuds with an external or internal stakeholder and falls into one of three categories:

- **Dispute:** a disagreement with, a challenge to, or an appeal of a CTP decision or action
- **Complaint:** an expression of dissatisfaction with a CTP policy or action
- **Inquiry:** an issue that does not rise to the level of a complaint or dispute, such as an inquiry about the regulatory process

74% Percent of contacts that reached resolution [1]

Resolution of contact addressed indicates:

- CTP Ombuds responded to the inquiry
- CTP Ombuds referred the inquiry to a more appropriate specialist
- The stakeholder withdrew the inquiry

75% Percent of contacts from tobacco companies (manufacturers, retailers, or representative)

72% Percent of interactions about the top four topics of interest

1 Some of the contacts may have been opened in one calendar year and rolled over to the next until resolution is reached.

2022-2024 TOPICS OF INTEREST

The CTP Ombuds may exchange several phone calls or emails with a single stakeholder, and these follow-up communications are counted as a single contact for the purposes of the annual report. If the stakeholder raises a substantially different issues, this would be logged as a new contact. When an inquiry, complaint, or dispute is not fully resolved by the end of the calendar year, the issue is held open into the following calendar year to continue working towards reaching resolution.

The top five topics from 2022-2024 were:

- Request for supervisory review
- Informal dispute discussion
- Retailer compliance and inspection
- Tobacco product application
- Non-tobacco flavored product regulation

Request for supervisory review: The primary topic of interest in the past several years was request for supervisory review filed pursuant to 21 CFR 10.75, which states that "An interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review." A supervisory review is an opportunity for stakeholders, such as a manufacturer or tobacco company representatives, to present why they do not agree with the agency's final action. The CTP Ombuds helps to resolve requests for supervisory review, while other CTP and FDA staff assist with reviewing and managing these requests. Before submitting a request for supervisory review, a stakeholder may contact the CTP Ombuds to discuss the process beginning to end as well as which documents they may want to request through an FDA Freedom of Information Act request.

Informal dispute discussion: A party can contact the CTP Ombuds for an informal dispute discussion to gain insight on practices in place and options available after a decision is made that the party disagrees with. Parties commonly ask for an informal dispute before submitting a formal request for supervisory review or scientific dispute.

Retailer compliance and inspection: Retailer compliance and inspection includes reporting underage sales, packaging and tobacco product issues, follow-up inquiries on CTP-issued warning letters and other issues addressed by the Office of Compliance and Enforcement. Retailer compliance issues are among the issues that can be entered in to CTP's potential tobacco product violation reporting portal.

Tobacco product application: Tobacco product application inquiries are best addressed by the assigned regulatory health project manager as the subject matter expert in the Office of Science. If it is unclear who to contact, there have been issues getting in touch with someone, or the question is very broad then reaching out to the CTP Ombuds would be a beneficial next step.

Non-tobacco flavored product regulation: The distribution of stakeholders contacting the CTP Ombuds and the topic of interest commonly reflects CTP's actions and announcements that year. For example, non-tobacco flavored product regulation became the second-most-frequent issue in 2022 following the announcement of proposed FDA regulation of menthol in cigarettes. For the latest CTP announcements, please visit the CTP Newsroom.

2022 - 2024 Top 10 Topics of Interest