

PROTECTING PUBLIC HEALTH

Ensuring Compliance With Federal Tobacco Product Regulation

EVERY DAY IN THE UNITED STATES:



1,300+
people die due
to cigarette use¹



2,800+
youth under age 18 smoke
their first cigarette, and nearly
1,500 use smokeless tobacco
for the first time²



700+
youth under age 18 become
daily cigarette smokers²

Creating Powerful Change for a Healthier Future

To protect the public, especially youth, from the dangers of tobacco use, the Center for Tobacco Products (CTP) Office of Compliance and Enforcement (OCE) ensures that regulated industry complies with federal tobacco product regulation using a three-pronged approach:

- 1 Develop and provide compliance training and education.
- 2 Monitor regulated industry's compliance with the law through surveillance, inspections, and investigations.
- 3 Initiate advisory and enforcement actions such as issuing warning letters and seeking Civil Money Penalties against noncompliant industry, as appropriate.

Compliance and enforcement activities include, but are not limited to:



Inspecting manufacturing facilities and retail establishments



Reviewing industry submissions, registrations, and listings



Reviewing print and online advertising



Handling potential violation complaints from the public



Monitoring promotional activities



Educating retailers and small businesses on federal tobacco regulations

When CTP observes a violation, CTP takes action. We generally issue a Warning Letter to a company for first-time violations. CTP may subsequently initiate enforcement action for companies that continue to violate the law, such as:

- Civil money penalty (fine)
- Injunction
- No-tobacco-sale order
- Criminal prosecution
- Seizure

Enforcing the Law

As of September 1, 2015:



495,000

inspections of tobacco retailers have been conducted.



34,400

Warning Letters have been issued to retailers following compliance check inspections.



4,900

Civil Money Penalties have been issued to retailers for violating the law.



310

Warning Letters have been issued to online retailers stemming from surveillance activities.

Ensuring That Tobacco Products Stay Out of the Hands of Kids

To help end youth access to tobacco products, OCE investigates complaints from the public about potential violations.

The public, plays a vital role in helping us to identify possible violations of the laws we enforce. Protect kids by watching out for these violations, such as:



- Sales of cigarettes or smokeless tobacco to minors
- Sales of single cigarettes



- Sales of flavored cigarettes or flavored cigarette tobacco (except menthol)



- Offers of free samples of cigarettes
- Offers of free samples of smokeless tobacco, unless in a "qualified adult-only facility"

Reporting Violations to Help CTP



Fill out the Potential Tobacco Product Violations Reporting Form



Call the Tobacco Call Center toll-free at 1.877.CTP.1373



Send us a letter at:

Document Control Center
Center for Tobacco Products
Food and Drug Administration
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993



Email us at
CTPCompliance@FDA.hhs.gov

Determining a Course of Action

After FDA reviews a complaint, next steps may include:



Performing an inspection of a tobacco product manufacturer, distributor, or importer



Conducting a compliance check inspection of a tobacco retailer



Initiating monitoring and surveillance of a tobacco product manufacturer's or retailer's website

Additional Resources

- FDA.gov/tobacco
- [FDA Warning Letters](#)
- [Retailer Inspection Database](#)

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¹ U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.

² Substance Abuse and Mental Health Services Administration (SAMHSA). *Results from the 2012 National Survey on Drug Use and Health, NSDUH: Table 4.10A Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to the Age of 18, by Gender: Numbers in Thousands, 2012 and 2013*. Rockville (MD): U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, 2014. Retrieved on April 17, 2015 from <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2013.pdf>.



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