THE 5 Ws OF ADVERTISING AND LABELING COMPLIANCE CHECK INSPECTIONS

CENTER FOR TOBACCO PRODUCTS

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

AGENDA

- Types of Compliance Check Inspections
- **Who** conducts the inspections?
- **What** are the inspectors investigating?
- **Where** are inspections conducted?
- **When** will the inspections take place?
- **Why** does FDA conduct these inspections?
- Further Information Links
- Contacting CTP

TYPES OF COMPLIANCE CHECK INSPECTIONS

TYPES OF COMPLIANCE CHECK INSPECTIONS

- The Tobacco Control Act gives FDA authority to inspect retail establishments.
- CTP conducts two types of compliance check inspections to confirm retailer compliance with federal law:
  - Undercover Buy Inspections
  - **Advertising and Labeling Inspections**

5 Ws OF ADVERTISING AND LABELING INSPECTIONS

WHO

- Who conducts the Advertising and Labeling inspections?
  - FDA commissioned inspectors complete FDA training and conduct FDA inspections on behalf of the FDA.
  - FDA contracts with states, territories, and Tribes to inspect retail establishments within their jurisdictions, where feasible.
  - FDA awards contracts to third-party entities to hire commissionable inspectors to conduct compliance check inspections of tobacco retailers in those states and territories where FDA has not been able to contract with a state agency.
  - Inspectors conduct compliance check inspections of tobacco retailers and send evidence of potential violations to FDA for review.

WHAT

- What occurs during an Advertising and Labeling inspection?
  - A commissioned FDA inspector will issue an FDA Form 482 – Notice of Inspection to the establishment. Additionally, they will:
    - Introduce themselves by name, title, and organization, and provide credentials
    - Ask to speak with the most responsible person present
    - Ask the most responsible person present to provide:
      - Their name
      - The establishment's name, physical address, and telephone number
      - Ownership information
    - Sign the Notice of Inspection (Form FDA 482)
    - Give a copy to the most responsible person present
    - Inspect the retail establishment

WHAT

- The inspector will observe the method and manner that the retail establishment is selling regulated tobacco products. The inspection will check for compliance with FDA's laws and regulations such as:
  - DO NOT give away free samples of tobacco products, except for smokeless tobacco from a "qualified adult-only facility"
  - DO NOT break open cigarette or smokeless tobacco packages to sell products in smaller amounts
  - DO NOT sell cigarette packages containing fewer than 20 cigarettes
  - DO NOT sell single cigarettes (also called "loosies")
  - DO NOT sell cigarettes, cigarette tobacco, or roll-your-own tobacco that contains a characterizing flavor (except menthol or tobacco flavor).
  - DO NOT sell products that lack the required premarket authorization.
  - ENSURE that required warning statements on all tobacco products.

WHAT

- The inspector's role is to gather information. These observations are sent back to FDA for review.
- FDA will review the evidence and determine if any violations have occurred.
- A retailer will NOT be notified of any violations at the time of the inspection.

WHERE

- Where are Advertising and Labeling inspections conducted?
  - Advertising and Labeling inspections are conducted at brick-and-mortar tobacco retailer locations across the United States, U.S. territories, and on Tribal land.

WHEN

- When will these inspections occur?
  - Compliance Check Inspections are not preannounced to the retailer.

- When will I hear from FDA if potential violations are found during an Advertising and Labeling inspection?
  - Once FDA has reviewed the inspection evidence, if violations are found:
    - Generally, FDA sends Advisory Actions (*e.g.*, Warning Letters) for the first time an inspection reveals a violation of federal tobacco laws and regulations
    - Failure to promptly and adequately correct all violations and ensure compliance with all applicable laws and regulations may lead to:
      - Administrative Actions (*e.g.,* Civil Money Penalties or No-Tobacco-Sale Orders)
      - Judicial Actions (*e.g.*, seizure, injunction, or criminal prosecution)

WHEN

- Brick and mortar retailers can check their inspection history on the FDA ‘Compliance Check Inspections of Tobacco Product Retailers’ Database.

- Available at: https://timp-ccid.fda.gov/.

WHY

- Why does FDA conduct these inspections?
  - The Center for Tobacco Products (CTP) is responsible for carrying out the Family Smoking Prevention and Tobacco Control Act.
  - In 2009, the Family Smoking Prevention and Tobacco Control Act,(TCA), amended the Federal Food Drug, and Cosmetic Act (FD&C Act) to give the FDA authority to regulate the manufacture, distribution and marketing of cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and other tobacco products that the agency, through regulation, deems to be subject to the law.

WHY

- The 2016 Deeming Rule extends FDA's regulatory authority to cover additional products, except their accessories, that meet the definition of a tobacco product under Section 201(rr) of the FD&C Act. These deemed products include: e-cigarettes, pipe tobacco, cigars, hookah and oral nicotine products.

- On Dec 20, 2019, the President signed legislation raising the federal minimum age for sale of tobacco products from 18 to 21 years. This legislation (known as "Tobacco 21" or "T21") became effective immediately, and it is now illegal for a retailer to sell any tobacco product to anyone under 21.

- On March 15, 2022, the President signed legislation to clarify that FDA's tobacco product jurisdiction extends to tobacco products containing nicotine from any source, not just nicotine derived from tobacco. As such, retailers of tobacco products containing nicotine not made or derived from tobacco must ensure compliance with applicable requirements under the FD&C Act resulting from this law.

WHY

- FDA conducts these inspections to further CTP's mission to protect Americans from tobacco-related disease and death by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

- We hope retailers will partner with the FDA to help protect their communities by knowing the law, and making use of tools to prevent underage sales.

FOR FURTHER INFORMATION:

- Retail Sales of Tobacco Products
  https://www.fda.gov/tobacco-products/compliance-enforcement-training/retail-sales-tobacco-products
- Summary of the Federal Rules for Selling Tobacco Products
  https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores
- Market and Distribute a Tobacco Product Summary
  https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product
- “This is Our Watch” Campaign for Retailers
  https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch
- Social Media Links (e.g., Twitter, Facebook, YouTube)
  https://www.fda.gov/tobacco-products/contact-ctp/connect-ctp
- Sign up for CTP E-mail Updates
  https://www.fda.gov/tobacco-products/ctp-newsroom

WHAT IS THE BEST WAY TO CONTACT FDA WITH ADDITIONAL QUESTIONS?

For additional questions, you can contact FDA:

- CTP General E-mail: AskCTP@fda.hhs.gov
- Call: 1-877-287-1373 (9am EST- 4pm EST)
- For Small Business Assistance E-mail: SmallBiz.Tobacco@fda.hhs.gov