



FDA TOBACCO INSPECTION PROGRAM

WI Wins Focus Call

June 23, 2016

Types of Inspections

1. Advertising and Labeling
2. Undercover Buys

Which can be either...

- Routine
- Compliance Follow-Up
- Complaint Follow-Up

FDA Public Inspection Website

http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm

The screenshot displays the FDA's public inspection website. At the top, the U.S. Department of Health & Human Services logo is visible, along with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A search bar with a "SEARCH" button is located in the top right. Below the header, a navigation menu includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main heading reads "Compliance Check Inspections of Tobacco Product Retailers (through 05/31/2016)". A breadcrumb trail shows the path: FDA Home > Tobacco Products > Information about Compliance Check Inspections. On the left, a "Search Inspection Decisions" form includes fields for Retailer Name, City, State (dropdown), Zip, Decision Type (dropdown), Decision Date (calendar), Minor Involved (dropdown), and Sale to Minor (dropdown). A "Search" button is at the bottom of the form. To the right is a map of the United States with "Map" and "Satellite" tabs. A "Reset Map and Clear Form" button is located below the map. At the bottom left, there is a link to "Export Data to Excel by Fiscal Year".

FDA Deeming Regulation

	 CIGARETTES	 SMOKELESS TOBACCO	 CIGARS	 E-CIGARETTES & OTHERS
Minimum sales age of 18 and age verification under 27	✓	✓	✓	✓
Prohibition on vending machine sales	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities
Prohibition on self-service displays	Allowed in adults-only facilities	Allowed in adults-only facilities		
Minimum package size requirements	✓			
Prohibition on breaking packages by retailers (e.g., sales of loosies)	✓	✓		
Prohibition on free samples	✓	Allowed in qualified adults-only facilities	✓	✓
Prohibition on characterizing flavors	Menthol and tobacco allowed			
Mandatory warning labels on packages and advertisements	9 Rotating warnings	4 Rotating warnings	6 Rotating warnings ¹	1 Static warning
Prohibition on brand names on non-tobacco products and brand name sponsorship of sporting and cultural events	✓	✓		
Required notice of advertising in any non-traditional medium	✓	✓		

Retailer Questions about Deeming Regulations

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>

The screenshot shows the FDA website's 'Tobacco Products' section. The header includes the FDA logo, 'U.S. Food and Drug Administration', and 'Protecting and Promoting Your Health'. A search bar is visible. The main navigation menu includes 'Home', 'Food', 'Drugs', 'Medical Devices', 'Radiation-Emitting Products', 'Vaccines, Blood & Biologics', 'Animal & Veterinary', and 'Cosmetics'. The current page is 'Tobacco Products' with a sub-menu for 'Compliance, Enforcement & Training'. A sidebar on the left lists various topics like 'Compliance & Enforcement', 'FDA Tobacco Compliance Webinars', and 'Report Potential Tobacco Product Violation'. The main content area features a red banner with the text: 'FDA vigorously enforces the Tobacco Control Act, which provides FDA with a wide array of powerful regulatory tools to protect the health of all American families.' Below this is a section titled 'Compliance and Enforcement' with a sub-header 'Compliance, Enforcement & Training'. The text states: 'FDA closely monitors retailer, manufacturer, importer, and distributor compliance with Federal tobacco laws and regulations and takes corrective action when violations occur.' It then lists a 3-pronged approach to help industry comply with the law by:

- developing and providing compliance training and education
- monitoring regulated industry's compliance with the law through surveillance, inspections, and investigations
- taking action when necessary, including:
 - [Warning Letters](#)
 - [Civil Money Penalty \(CMP\) Complaints](#)
 - [No-Tobacco-Sale Order \(NTSO\) Complaints](#)
 - Seizures, Injunctions, and Criminal Prosecution

Below this is a section titled 'Helping Retailers Comply with FDA Regulations' with the text: 'Retailers play an important role in protecting the health of young people by following the law and refusing to sell regulated tobacco products to anyone under the age of 18. Find more information on our website, including:'

- [Retailer Education Materials](#)

On the right side of the page, there is a graphic titled 'PROTECTING PUBLIC HEALTH' with the subtitle 'Ensuring Compliance With Federal Tobacco Regulations'. It features statistics: '13,000+ tobacco products on the market', '2,500+ tobacco products with health warnings', and '100+ tobacco products with graphic warnings'. It also includes a call to action: 'Ensuring America's Children are Protected from Tobacco'.

Retailer Questions about Deeming Regulations

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm249332.htm>

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics

Tobacco Products

Tobacco Products [en Español](#)

Home > Tobacco Products > Compliance, Enforcement & Training > Retail

Retail

- Retailer Education Materials
- Retailer Overview of FDA Regulations for Selling Tobacco Products
- Retailer Regulations and Guidance
- Retailer Training and Enforcement**
- Tobacco Retailer Warning Letters Overview

Retailer Training and Enforcement

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Retailers play a critical role in protecting public health and creating powerful change leading to a healthier future for all families.



Overview

To help retailers better understand their responsibilities under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and comply with the law, FDA provides webinars, training videos, and guidance documents. These resources help to educate retailers and their employees about the Tobacco Control Act and tobacco regulations. FDA also works with state regulators to enforce federal regulations to reduce the harm of tobacco.

Retailer Compliance Training

- FDA hosts a [webinar](#) series to educate retailers on federal tobacco regulations and steps they can take to comply.



FDA Deeming Regulation & WI Wins

- Compliance Checks
- Outreach Opportunities
 - Verify Age/ID
 - Media – Press Release Template

Questions?





Contact Us!

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