

# THE NEW FDA TOBACCO LAWS

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# FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

- ✘ June 11, 2009 – U.S. Senate voted 79-17 to approve the bill (H.R. 1256/S. 982)
- ✘ June 12, 2009 – U.S. House of Representatives voted 307-98 to approve the identical bill.
- ✘ Sponsored by U.S. Reps. Henry Waxman (D-CA) and Todd Platts (R-PA) and the late U.S. Senator Edward Kennedy (D-MA).
- ✘ Signed into law on June 22, 2009
- ✘ Took effect June 22, 2010

# WHAT THE LAW DOES

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- ✘ Gives FDA the authority to regulate the manufacture, marketing and sale of tobacco products
- ✘ Tobacco products are regulated under a new standard – “appropriate for the protection of health”
- ✘ Creates a new branch within FDA specifically charged to monitor compliance with new FDA tobacco laws – “The Center for Tobacco Products.”

# THE LAW

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- ✘ Restricts tobacco marketing and sales to youth
- ✘ Grants the FDA authority to further restrict tobacco marketing
- ✘ Requires detailed disclosure of ingredients, nicotine and harmful smoke
- ✘ Allows FDA to require changes to tobacco products to protect the public health

# THE LAW

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- ✘ Regulates “reduced harm” claims about tobacco products to prevent inaccurate and misleading claims
- ✘ Requires bigger, bolder health warnings
- ✘ Fully funds FDA regulation of tobacco products through a user fee on manufacturers of cigarettes, cigarette tobacco and smokeless tobacco.
- ✘ Requires producers of new or modified tobacco products to obtain authorization before marketing their products.
- ✘ Preserves state and local authority



## ✘ Age & ID

- + Cigarettes and smokeless tobacco may not be sold to anyone younger than 18 years of age
- + Require retailers to verify age for all over-the-counter sales and provide for federal enforcement and penalties against retailers who sell to minors
  - ✘ Photographic identification

## ✘ Packaged & Unpackaged Cigarettes & Smokeless

- + Ban on sell of single cigarettes or packages containing fewer than 20 cigarettes except in vending machines in adult-only facilities
- + Ban on selling of unpackaged smokeless tobacco or packages of smokeless tobacco that are smaller than packages distributed by the manufacturer for individual use
- + Restrict vending machines and self-service displays to adult-only facilities



## ✘ Free Samples, Rebates, or Regulations of Coupons by Mail or Retailers

- + Distribution of free cigarettes is prohibited
- + Free samples of smokeless tobacco products may be distributed only in qualified adult only facilities and not more than 1 package or 0.53 ounces (15 grams) per individual per day.
- + Ban on free samples of smokeless tobacco to a sports team or entertainment group, or at any football, basketball, soccer, or hockey event
- + Ban on mail-order redemption of coupons and free samples of cigarettes or smokeless tobacco by mail
- + Ban free giveaways of any non-tobacco items with the purchase of a tobacco product or in exchange for coupons or proof of purchase



## ✘ Advertising and Labeling

- + Audio advertisements for cigarettes or smokeless tobacco may no include music or sound effects.
- + Video advertisements for cigarettes or smokeless tobacco may no use color, but rather are limited to static black text on a white background.
- + Limit advertising in publications with significant teen readership as well as outdoor and point-of-sale advertising, except in adult-only facilities, to black-and-white text only.
- + ***Ban outdoor advertising near schools and playgrounds after further FDA review.***
- + Ban all remaining tobacco-brand sponsorship of sports and entertainment events



- ✘ Secretary of Health and Human Services authority to develop regulations that:
  - + Impose restrictions on advertising and promotion of tobacco products to the full extent permitted by the First Amendment
  - + Based on the protection of public health
  - + Provide the flexibility to respond to tobacco industry attempts to circumvent new restrictions



- ✘ Existing tobacco products by brand and quantity in each brand
- ✘ Any changes to products



- ✘ All current and future products
- ✘ FDA has the authority to change nicotine yields – Congress maintains the authority to ban nicotine completely

## REGULATE “REDUCED HARM”

- ✘ Prohibits the use of the terms “light”, “mild”, and “low”
- ✘ Manufacturer must file an application and receive an order before marketing any product presented as “modified risk”

# “COLOR CODING” OF LIGHT/LOW PRODUCTS



<http://www.fastcompany.com/blog/lucas-conley/advertising-branding-and-marketing/smoke-and-mirrors-smoke-signals-tobacco-two-ste>



- ✘ Large text warning labels on smokeless tobacco – 30% of principal display and 20% of advertising
- ✘ By 2012, large graphic cigarette warning labels – top 50% of front and back panels of pack and 20% of advertising
- ✘ Authority to revise requirements

# WARNINGS “BEFORE” AND “AFTER”



**BEFORE,  
DURING  
AND AFTER**  
BOLDLY GO EVERYWHERE

**BREAK FREE**

**EXPERIENCE CLEANER  
TOBACCO ENJOYMENT**  
Small-pouches. MODERN tobacco that's spit-free.  
MESS-FREE and cold cold for FRESHNESS.

**WARNING:**  
THIS PRODUCT  
MAY CAUSE  
MOUTH CANCER

camelonus.com



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Small-pouches. MODERN tobacco that's spit-free.  
MESS-FREE and cold cold for FRESHNESS.

camelonus.com

**WARNING: This product can cause  
gum disease and tooth loss.**



# PROPOSED CIGARETTE WARNINGS





- ✘ Doesn't preempt state and local government from enacting other tobacco control measures
  - + Tobacco taxes
  - + Smoke-free workplaces
  - + Fire-safety standards for cigarettes
  - + Measures related to sales, distribution, and possession, exposure to, or access to tobacco products
- ✘ New authority to restrict time, place and manner of cigarette advertising, consistent with the First Amendment

# NOT INCLUDED IN FDA REGULATION



## How an electronic cigarette works

The electronic cigarette contains a battery that activates a heating device, atomizing liquid nicotine inside a cartridge and producing a vapor that is inhaled.



Source: alhookah.net

Tim Summers / The Detroit News

# ENFORCEMENT

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- ✘ FDA Inspections and contracts with state to inspect retail establishments within the state, to the extent feasible
- ✘ Retail establishments are responsible for providing training to their employees. FDA intends to publish guidance to assist retailers in complying with the law.
- ✘ FDA has a variety of enforcement tools including:
  - + Civil money penalties
  - + Warning letters
  - + Seizure
  - + Injunctions
  - + Criminal prosecution.

# TOBACCO RETAILER'S RESPONSIBILITIES

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- ✘ not to sell cigarettes or smokeless tobacco to anyone younger than 18 years of age;
- ✘ verify that any person buying cigarettes or smokeless tobacco is at least 18 years old by means of photographic identification check identification for all individuals who are under the age of 27;
- ✘ sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange between you and your customer, without the help of any electronic or mechanical
- ✘ not break open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or any number less than 20 or any quantity of smokeless tobacco

# ***RETAILER'S RESPONSIBILITY CONCERNING POINT OF SALE DISPLAYS, ADVERTISING AND LABELING***

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- ✘ Each retailer must ensure that all self-service displays, advertising labeling, and other items located in its establishment that do not comply with the regulations are removed or are brought into compliance
- ✘ It should be noted also that the regulations also require manufacturers to remove items that they own if those items violate the regulations.

# FDA TOBACCO RETAILER EDUCATION

## DON'T LET MINORS BUY TOBACCO. IT'S THE LAW.



Break the chain of tobacco addiction. Keep tobacco out of the hands of America's youth. It's the right thing to do.

For tools and tips: [www.fda.gov/BreakTheChain](http://www.fda.gov/BreakTheChain)



## DO YOU SELL TOBACCO PRODUCTS?



Then you must comply with these federal laws:\*

- Check ID of everyone appearing under age 27 who attempts to purchase cigarettes or smokeless tobacco.
- Only sell cigarettes and smokeless tobacco to anyone age 18 or older. (Retailers must comply with more restrictive state or local laws. For example, the legal age in Alabama, Alaska, New Jersey, and Utah is 19.)
- Only sell cigarettes and smokeless tobacco in a direct, face-to-face exchange. (Vending machines and self-service displays are restricted to adult-only venues. Please note that tobacco vending machines are banned in some states.)
- Do NOT break open cigarette or smokeless tobacco packages to sell products in smaller amounts.
- Do NOT give away free samples of cigarettes or smokeless tobacco.
- Do NOT sell or give away items, such as hats or t-shirts, with tobacco brands or logos.
- Do NOT sell flavored cigarettes, such as strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee cigarettes.

\* This is only a summary of the laws. For the full list of federal laws, visit: [www.fda.gov/BreakTheChain](http://www.fda.gov/BreakTheChain).

\* Retailers must also follow state tobacco laws. Please check with your state tobacco control office for more information.

### Why Are These Laws Important?

These laws are designed to make tobacco products less accessible and less attractive to youth. Every day nearly 4,000 kids try their first cigarette and 1,000 kids become daily smokers. Many of these children will become addicted before they are old enough to understand the risks, and they will ultimately die of tobacco-related diseases. As a retailer, you play an important role in protecting children and adolescents by complying with the law.

### Show Your Support

Place these stickers on cash registers or counters.

### Join Us in Breaking the Chain of Tobacco Addiction

Join the FDA retailer education campaign, Break the Chain of Tobacco Addiction. Visit [www.fda.gov/BreakTheChain](http://www.fda.gov/BreakTheChain) for free tools, tips, resources, and contests.

### Do You Have Questions?

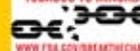
Contact the FDA Center for Tobacco Products

Phone: 1-877-287-1373 E-mail: [AaC1P@fda.hhs.gov](mailto:AaC1P@fda.hhs.gov)

Website: [www.fda.gov/BreakTheChain](http://www.fda.gov/BreakTheChain)

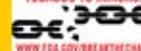
Mail: U.S. Food and Drug Administration  
Center for Tobacco Products  
8200 Corporate Blvd., Rockville, MD 20850

WE FOLLOW THE LAW.  
WE DON'T SELL  
TOBACCO TO MINORS.



[WWW.FDA.GOV/BREAKTHECHAIN](http://WWW.FDA.GOV/BREAKTHECHAIN)

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[WWW.FDA.GOV/BREAKTHECHAIN](http://WWW.FDA.GOV/BREAKTHECHAIN)

To order more, visit  
[www.fda.gov/BreakTheChain](http://www.fda.gov/BreakTheChain)



## ✘ Support for new FDA regulation

- + Contact with local tobacco vendors regarding education
- + Press release from your coalitions
- + Educating the public about changes

## ✘ Strengthen Synar efforts

- + Help identify all tobacco outlets in your region and share information with state and ABC
- + Maintain contact with local tobacco vendors
- + Coalition sponsored compliance checks



- ✘ Partner with Local Substance Abuse Coalitions
  - + Smoke-free ordinance efforts
  - + Tobacco-Free schools efforts
  
- ✘ Utilize youth advocates
  - + Educate about FDA
  - + Support H.O.T. youth movement

<http://www.fda.gov/TobaccoProducts>

Center for Tobacco Products 1-877-CTP-1373

U.S. Department of Health & Human Services [www.hhs.gov](http://www.hhs.gov)

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**For Retailers**  
The tobacco retailer community plays a direct role in helping us protect kids from tobacco. Guidance for industry on the new rules to protect kids is available.

**Protecting Kids from Tobacco**  
The new FDA rule is designed to significantly curb access to and the appeal of cigarettes and smokeless tobacco products to children and adolescents in the United States.

**Tobacco Control Act One Year Anniversary**  
The FDA has taken several important steps in an effort to prevent our children from becoming the next generation of Americans to die prematurely from tobacco use.

**Spotlight**

- FDA Marks First Anniversary of Tobacco Control Act
- Get the Tobacco Regulations, Education, Prevention and Control Widget
- Web-Based Public Meeting on Issues Related to Development of Enforcement Plan

**Tools**

- Calculator: How Much Does Smoking Cost You?
- Reasons to Quit
- How Does Smoking Affect Your Lifespan?

**Contact Us**

**Tobacco**

- 1-877-CTP-1373
- 1-877-287-1373
- (7:30am EDT-6pm EDT)

For General Inquiries:  
AskCTP@fda.hhs.gov  
Center for Tobacco Products  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

**News & Events (Tobacco)**  
Press Releases, FAQs, Progress Reports, and Meetings & Conferences

**Guidance, Compliance & Regulatory Information (Tobacco)**  
FDA & Tobacco Regulation: Legal, Regulatory, and Policy issues on the Family Smoking Prevention and Tobacco Control Act of 2009.

**Labeling (Tobacco)**  
The Tobacco Control Act requires changes to the labeling and advertising of certain tobacco products.

**Protecting Kids from Tobacco**  
FDA is working to protect the health of America's children and ultimately reduce the burden of illness and death caused by tobacco use.

**Resources for You (Tobacco)**  
For Consumers, Industry, Retailers, and Manufacturers and Health Professionals

**Resources for You**

- For Industry
- Sign Up for E-mail Updates on Tobacco Products
- About the Center for Tobacco Products
- Tobacco Control Act

Search Tobacco Products  go

**Tobacco Products Scientific Advisory Committee**

- Roster of the Tobacco Products Scientific Advisory Committee
- Tobacco Products Scientific Advisory Committee
- July 15-16 Meeting of the Tobacco Products Scientific Advisory Committee Meeting Announcement
- 2010 Meeting Materials, Tobacco Products Scientific Advisory Committee

Page Last Updated: 06/22/2010  
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

# CENTER FOR TOBACCO WORK PRODUCTS

- ✘ The Industry Menthol Report
- ✘ Evaluation of E-Cigarettes
- ✘ Tobacco Retailer Education Program – “Break The Chain.”

# CENTER FOR TOBACCO PRODUCTS E-MAIL LIST

✘ <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm>

# OTHER RESOURCES

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- ✘ Campaign for Tobacco Free Kids
  - + <http://www.tobaccofreekids.org>
  
- ✘ American Legacy Foundation
  - + <http://www.legacyforhealth.org>
  
- ✘ Center for Disease Control and Prevention
  - + <http://www.cdc.gov/Features/TobaccoControls>

# **KY-ABC and The FDA Tobacco Regulations**

Josh Crain Alcoholic Beverage Control

**KY ABC AND FDA TOBACCO REGULATIONS**

# STATES THAT HAVE BEEN AWARDED FEDERAL CONTRACTS TO FUND ENFORCEMENT OF THE NEW FDA REGULATIONS

Arkansas

Arizona

Colorado

Idaho

Kansas

Alabama

Maine

Maryland

Massachusetts

Mississippi

Missouri

Illinois

Pennsylvania

Tennessee

Washington

# KY ABC'S APPROACH

- ✘ Developing a retailer list
- ✘ Use current investigators
- ✘ Utilize equipment and resources

# TWO TYPES OF FDA CHECKS

1) Undercover Buy Assignments

2) Advertising and Labeling Assignments

# UNDERCOVER BUY ASSIGNMENTS

- ✘ Focus on point of sale
- ✘ Minimum of 20% of tobacco outlets checked – annually
- ✘ Checks done in a covert manner

# FDA ADVERTISING REGS

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- ✘ **Are vendor posters and displays placed in a retailer's window or placed in other locations throughout a retailer's facility in violation of the law if they are in color or contain imagery?**

Yes, advertising and labeling with imagery and color are prohibited under the regulations.

- ✘ **What are the advertising restrictions for “qualified adult-only facilities?”**  
Under section 1140.16(d)(2)(C) of the regulations, qualified adult-only facilities are not permitted to display on the exterior of the facility tobacco product advertisements; a tobacco product brand name except for purposes of identifying an area or enclosure as an adult-only facility; or words that imply that the manufacturer, distributor, or retailer has a sponsorship that violates section 1140.34(c).

# FDA ADVERTISING REGS

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- **What is the manufacturer's responsibility concerning point of sale displays, advertising and labeling?**  
Under section 1140.12 of the regulations, manufacturers must remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the regulations.
- **What is the retailer's responsibility concerning point of sale displays, advertising and labeling?**  
Under section 1140.14(e) of the regulations, each retailer must ensure that all self-service displays, advertising, labeling, and other items located in its establishment that do not comply with the regulations are removed or are brought into compliance.

# PENALTIES

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- ✘ First offense – Warning Letter from FDA
- ✘ Second offense w/in 12 months - \$250.00
- ✘ Third offense w/in 24 months - \$500.00
- ✘ Fourth offense w/in 24 months - \$2,000.00
- ✘ Fifth offense w/in 36 months - \$5,000.00
- ✘ Sixth offense w/in 48 months - \$10,000.00

## Weigel's #12 4/21/11

Knoxville, TN 37921

Dear Sir or Madam:

On March 16, 2011, inspectors representing the United States Food and Drug Administration (FDA) completed a compliance check inspection of your retail establishment located at 5621 Western Ave., Knoxville, TN 37821. Your retail establishment sells cigarettes and/or smokeless tobacco products. The sale, distribution, advertising, and promotion of your tobacco products must comply with the Federal Food, Drug, and Cosmetic Act (Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, found at Title 21, **Code of Federal Regulations** (C.F.R.), Part 1140. You are legally responsible for complying with these regulations and for ensuring that your employees comply with these regulations.

This compliance check inspection revealed that your tobacco products are misbranded within the meaning of section 903(a)(7)(B) of the Act, 21 U.S.C. § 387c(a)(7)(B), in that they are sold or distributed in violation of 21 C.F.R. Part 1140. The violations identified at your retail establishment include, but are not limited to, the following:

1. Failure to ensure that the cigarettes and/or smokeless tobacco you sell comply with all applicable requirements under 21 C.F.R. Part 1140, as required by 21 C.F.R. § 1140.10. The deviations below are examples of your violation of this part.
2. Failure to sell cigarettes or smokeless tobacco in a direct, face-to-face exchange without ensuring that no person younger than 18 years of age is present or permitted to enter, at any time, as required by 21 C.F.R. §§ 1140.16(c)(1) and 1140.16(c)(2)(ii).

For example, your establishment has a self-service display that provides a consumer direct access to tobacco products without ensuring that no person younger than 18 years of age is present or permitted to enter at any time. It is your responsibility to take appropriate measures, such as checking identification upon entry, to ensure that no person younger than 18 years of age is present or permitted to enter the establishment at any time.

# CONTACT INFORMATION

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