THE NEW FDA TOBACCO LAWS

Amy M. Jeffers, MA, CPS
Tobacco Prevention Enhancement Site (PES),
P. O. Box 790
Ashland, KY 41102
606.329.8588 Ext. 4099
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

- 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.”
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
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 of 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
 Requires detailed disclosure of ingredients, nicotine and harmful smoke

- 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
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

- 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”
CIGARETTE PACKS NOW UNDER FDA REGULATION
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.

Liquid nicotine cartridge  Inhaler  Atomizer/heating device  Lithium battery  Tip lights up
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

- 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.
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

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**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.

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

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**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 1,800 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.

**Do You Have Questions?**

Contact the FDA Center for Tobacco Products

Phone: 1-877-287-1373
E-mail: AskCTPHda.hhs.gov
Website: www.fda.gov/BreakTheChain

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**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 for free tools, tips, resources, and contests.

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- 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
The Industry Menthol Report
Evaluation of E-Cigarettes
Tobacco Retailer Education Program – “Break The Chain.”
http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm
OTHER RESOURCES

- 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**

- 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).
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.
PENALITIES

- 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
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.
Josh Crain
Josh.Crain@ky.gov
502-782-1032

Tonya Green
Tonya.Green@ky.gov
502-782-1039