

Arizona Department of Health Services

FDA

Tobacco Retailers Compliance Program

Presentation

June 29, 2011



*Leadership for a Healthy Arizona*

Revised 06/27/11

# FDA

## Retail Tobacco Compliance Program

In contract with

## Arizona Department of Health Services

## Office of Inspection and Compliance



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# Office of Inspection and Compliance Office Staff

Harmony Duport - Office Chief

FDA Tobacco Compliance Program Manager

Jack Doyle 602) 364-3847

FDA Commissioned Officers

Diane Burkett - Inspector 602) 364-3133

Heather James - Inspector 602) 364-3657



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# Federal Tobacco Control Act (TCA)

## History

- 1906 *Pure Food and Drug Act* – First comprehensive Federal consumer protection law
- 1938 *Food, Drug and Cosmetic Act (FD&C)* – Expansion and strengthening of the 1906 law
- 2009 *Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA)* – Amendment to the FD&C Act establishing the legal framework for, and giving authority to, the FDA to regulate tobacco products

# Federal Tobacco Control Act

## Purposes

- To protect the public from the health risks associated with long-term tobacco use
- To prevent youth from initiating tobacco use, thereby preventing them from becoming addicted to tobacco products.

# Federal Tobacco Control Act

## Definitions

### Flavored Tobacco

Cigarettes or any component parts (tobacco, filter, paper) cannot contain any additives or flavors (other than tobacco and menthol) or an herb or spice

Examples include:

Strawberry, Grape, Orange, Clove, Cinnamon, Pineapple, Vanilla, Coconut, Licorice, Cocoa, Chocolate, Cherry or Coffee

# Federal Tobacco Control Act

## Definitions

### Modified Risk Tobacco Products

No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product

“Modified Risk Tobacco Product” means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco related disease associated with tobacco products

Examples Include:

Light, Low, Mild

# Products *COVERED* by the FDA Retail Tobacco Program

- Cigarettes
  - Smokeless Tobacco
    - Roll-Your-Own Tobacco

# Products *NOT* Covered by the FDA Retail Tobacco Program

- Cigars
- Pipe Tobacco
- Nicotine Patch
- Dissolvable Tobacco
- Hookah Tobacco
- Dried Tobacco Leaf
- Electronic Cigarette

# MISSION STATEMENT

To conduct inspections in retail establishments that sell and advertise cigarettes, smokeless tobacco and roll-your-own tobacco products to determine compliance with the provisions cited by Federal guidelines and submit observations and inspection results to FDA



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# FDA Retail Tobacco Goals for Arizona 2011

- Inspect 1000 retail establishments statewide this year, including retailers in major cities, suburban, rural and urban areas.
- A minority community inspection rate of 20%

# 2 Types of Inspections

## Undercover Buys

- Conducted with undercover youth buyers ages 15-17

## Advertising & Labeling

- Conducted by FDA Inspectors only

# Undercover Buys

## Primary Focuses

1. Test tobacco retailers to determine if they are asking for verification of age (i.e. asking for photo ID of anyone suspected of being under 27 years of age)
2. Did the retailer sell a tobacco product to the youth inspector

# Undercover Buys

## Secondary Focus

- If the minor was successful in purchasing a tobacco product, was it one of the following:
  - Product labels “low” “light” or “mild” or similar
  - Flavored tobacco product other than tobacco or menthol
  - Open or partially opened package of cigarettes with less than 20
  - Open or partially opened or packaged smaller than smallest manufactured amount of smokeless tobacco
  - Non-tobacco gift or item in consideration of the tobacco purchase?  
(i.e. a lighter)
  - Free samples of cigarettes or smokeless tobacco  
( Except Buy-one-get-one-free)

# Undercover Buys

## Youth Inspectors

- Youth Inspectors will be supplied by pre-existing partnerships with Community Based Organizations in conjunction with Synar
- Youth will be between the ages of 15 – 17
- All youth will appear their age
- Youth inspectors will respond truthfully if asked their age by a retailer
- Youth inspectors will provide their ID if asked by a retailer
- Will be trained by the State
- Blends in with the community being inspected

*\* There will be no attempt at deception during these inspections!!*

# Advertising & Labeling

## Primary Focus

- To determine a retailer's compliance with advertising and labeling requirements of the Tobacco Control Act
- Sales to underage youth are covered in the Undercover Buy therefore these inspections do not include minors

# Advertising & Labeling

## Tobacco Products

A & L Inspections check for the following, which are NOT allowed by the TCA:

- Open, sell or distribute single cigarettes or any package with less than 20 cigarettes
- Offer open or partially opened or packaged smaller than smallest manufactured amount of smokeless tobacco
- Have visible inventory of products labeled “low” “light” or “mild” or similar
- Offer a cigarette or any component parts (tobacco, filter, or paper) that contains any flavor other than tobacco or menthol

# Advertising & Labeling

## Non-Tobacco Promotions

A & L Inspections check for the following, which are NOT allowed by the TCA:

- Offer any non-tobacco gift or item in consideration for purchasing cigarettes or smokeless tobacco
- Sponsor any athletic, musical, artistic, social or cultural event
- Sponsor any entry or team in any event which the tobacco brand name, logo, symbol, motto, selling message, etc. is identifiable

# Advertising & Labeling

## Impersonal Modes of Sale

- TCA states that retailers **MUST** have direct, face-to-face sales for tobacco products
- The exception is for impersonal modes of sale such as vending machines and self service displays
  - **HOWEVER**, this exception **ONLY** applies to retailers who do not allow minors under the age of 18 into their facility **AT ANY TIME**.
  - Bars, nightclubs, etc. who allow minors in with the company of an adults are therefore **NOT** covered by this exception.

# Flow of Information

Inspectors

- Conduct Retailer Inspections

State Program  
Manager

- Submits Inspections to FDA

FDA

- Determines Appropriate Actions and/or Penalties

# FDA Penalties

- Warning Letter (Published on FDA website)
- Civil Money Penalties
- No-Tobacco-Sale Order
- Seizure of Illegal Products
- Injunction
- Criminal Prosecution

# AZ FDA Program To Date

- Contract awarded to Arizona in September 2010
- Staff hired in December 2010
- Training and commissioning until late January 2011
- Inspections began in February 2011
- Undercover Buys
  - 428 completed inspections
  - 12 FDA issued warning letters
- Advertising and Labeling inspections
  - 557 completed inspections
  - 1 FDA issued warning letter

# Confidential Information

❖ The FDA Program Guidelines PROHIBIT the release of information on inspections or actions taking in response to inspections UNTIL the FDA has made public those records/actions

# Questions?

A white sunburst graphic with multiple rays emanating from a central point, positioned above a blue curved banner.

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