



Compliance Training for Retailers July 2010

Ann L. Simoneau, J.D., Acting Director
Valerie L. Whipp, State Programs
Group Leader

Office of Compliance and Enforcement
Center for Tobacco Products



Agenda

- FDA 101
- Final Rule (formerly 1996 Rule)
- Flavored Cigarette Ban
- Light, Low, Mild Restrictions
- Tobacco Retailer Training Program



NEW Slide 3 FDA 101

Who is FDA?

- FDA is a federal agency within the Department of Health and Human Services that regulates various commodities including drugs, medical devices, food, dietary supplements, cosmetics, vaccines, blood, biologics, animal and veterinary medicines, radiation-emitting products, and, most recently, tobacco products marketed to consumers in the United States.



NEW slide 4 FDA 101

Laws

Statutes

Example: Food, Drug, and Cosmetic Act (FD&C Act)

Regulations

Example: Title 21 of the Code of Federal Regulations
(21 CFR)

Guidances

Provides guidance to regulated industry on how to comply with statutory or regulatory requirements.



NEW slide 5 FDA 101

- FDA granted the authority to regulate tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)
- President Obama signed new law on June 22, 2009

NEW slide 6 FDA 101

The Tobacco Control Act Rule

- Required FDA to re-issue the 1996
- Requires FDA to contract with States, to the extent feasible, to carry out inspections of retailers within that State in connection with the enforcement



FDA 101

Questions





Final Rule (former 1996 Rule)

*Regulations Restricting the Sale
and Distribution of Cigarettes and
Smokeless Tobacco to Protect
Children and Adolescents*

21 CFR 1140

Effective 6/22/10



NEW Slide 8 Final Rule (former 1996 Rule)

*Regulations Restricting the Sale and
Distribution of Cigarettes and
Smokeless Tobacco to Protect
Children and Adolescents*

21 CFR 1140

Effective 6/22/10



Draft Guidance for Industry

*Compliance with Regulations
Restricting the Sale and
Distribution of Cigarettes and
Smokeless Tobacco to Protect
Children*



Guidance for Industry and FDA Staff

*Enforcement Policy Concerning
Certain Regulations Restricting
the Sale and Distribution of
Cigarettes and Smokeless
Tobacco*



Final Rule – Applicable

Manufacturers, distributors, and retailers who manufacture, distribute, or sell cigarettes or smokeless tobacco

Cigarettes (including roll-your-own tobacco)

Smokeless tobacco (including cut up, ground, powdered, or leaf tobacco that is intended to be placed in the nose or mouth, and includes moist snuff, snus, dry snuff, nasal snuff, loose leaf chewing tobacco, plug chewing tobacco, and twist chewing tobacco)



Final Rule – Not Applicable

Cigars and pipe tobacco which do not meet the definition of cigarettes

Final Rule – Two Main Parts

- (1) Access provisions, which consist of restrictions on the sale of cigarettes and smokeless tobacco products
- (2) Restrictions on advertising, marketing, and promotion of cigarettes and smokeless tobacco products



Final Rule-Age and Access Provisions

21 CFR 1140.14(a)

No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age.



Final Rule –Age and Access Provisions

21 CFR 1140.14(b)

Each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age.



Final Rule –Age and Access Provisions

21 CFR 1140.14(c)

A retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine or a self-service display).



Final Rule –Age and Access Provisions

21 CFR 1140.14(d)

No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or any number less than 20 cigarettes or any quantity of cigarettes or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use.



Final Rule –Age and Access Provisions

21 CFR 1140.14(e)

Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance.



Final Rule –Age and Access Provisions

21 CFR 1140.16(a)

A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.



Final Rule –Age and Access Provisions

21 CFR 1140.16(a)

Enforcement discretion.



Final Rule –Age and Access Provisions

21 CFR 1140.16(b)

No manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.



Final Rule –Age and Access Provisions

21 CFR 1140.16(c)

A retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer with two exceptions.



Final Rule –Age and Access Provisions

21 CFR 1140.16(c)- Two Exceptions

- (1) Mail-order sales are permitted, except that mail-order redemption of coupons and distribution of free samples through the mail are not permitted.
- (2) Vending machines and self-service displays are permitted in facilities where no one younger than 18 years of age is present or permitted to enter at any time.



Final Rule –Age and Access Provisions

21 CFR 1140.16(d)(1)

No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products with one exception.



Final Rule –Age and Access Provisions

21 CFR 1140.16(e)

No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance.



Final Rule –Age and Access Provisions

Questions





Final Rule –Promotion and Advertising Restrictions

21 CFR 1140.30(a)(1)

A manufacturer, distributor, or retailer may disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.



Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.30(a)(2)

A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in section 1140.30(a)(1) shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age.



Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.30(c)

The promotion and advertising restrictions do not apply to cigarette or smokeless tobacco packages.



Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.32

- Format and Content Requirements for Labeling and Advertising
- Enforcement discretion

Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.32(b)

Labeling and advertising

(1) In an audio format shall be limited to words only with no music or sound effects.

(2) Any audio with the video shall be limited to words only with no music or sound effects.



Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.34(a)

No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco or roll-your-own paper) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.



Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.34(b)

No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.



Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.34(c)

No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.



Final Rule – Promotion and Advertising Restrictions

21 CFR 1140.34(c)

Manufacturers, distributors, or retailers may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Final Rule – Promotion and Advertising Restrictions Questions





Flavored Cigarette Ban

Section 907(a)(1)(A) of the FD&C Act as amended by the Tobacco Control Act-

“...a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.”



Guidance for Industry and FDA Staff

General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)



Flavored Cigarette Ban– Applicable

All tobacco products with certain characterizing flavors that meet the definition of a “cigarette”

Cigarette

Cigarette tobacco

Roll-your-own tobacco

Loose tobacco

Rolling papers or filters intended for roll-your-own cigarettes



Flavored Cigarette Ban—Not Applicable

Bona fide pipe tobacco

Menthol cigarettes

Cigars



Flavored Cigarette Ban

Questions



Light, Low, Mild, or Similar Descriptor Restrictions

Section 911(b)(2)(A)(ii) of the FD&C Act prohibits the use of the descriptors “light,” “mild,” or “low,” or similar descriptors in tobacco product label, labeling, or advertising unless an FDA order is in effect under section 911(g) with respect to such product.



Guidance for Industry and FDA Staff

Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products



Light, Low, Mild, or Similar Descriptor Restrictions

6/22/10: Manufacturers may not
manufacture for sale and distribution

7/22/10: Manufacturers, including importers
of finished tobacco products, may not
introduce into domestic commerce



Light, Low, Mild, or Similar Descriptor Restrictions

Distributors, wholesalers, and retailers may distribute or sell off inventories for which tobacco products are labeled with the descriptors “light,” “low,” or “mild,” or any similar descriptor if the products were manufactured before 6/22/10 and shipped into the commercial market by the manufacturer, including an importer, before 7/22/10.



Light, Low, Mild, or Similar Descriptor Restrictions

Questions





Draft Guidance for Industry

Tobacco Retailer Training Programs

Tobacco Retailer Training Programs

Enforcement of the Final Rule under the Tobacco Control Act

- Warning Letter
- Civil Money Penalty
- No Tobacco Sale Order
- Seizure
- Injunction
- Criminal Prosecution



Tobacco Retailer Training Programs

Guidance to assist tobacco retailers in implementing effective training programs for employees to learn the Federal laws restricting the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, cigarettes and smokeless tobacco products.

Guidance also provides retailers with guidance on implementing effective training on how to request and verify the photo identification of purchasers younger than 27 years of age and how to refuse the sale of cigarettes or smokeless tobacco to purchasers younger than 18 years of age.

Tobacco Retailer Training Programs

- The FD&C Act does not require retailers to implement retailer training programs. However, the statute does provide for lower civil money penalties for violations of access, advertising and promotion restrictions promulgated under section 906(d) of the FD&C Act for retailers who have implemented a training program that complies with standards developed by the FDA for the programs. The FDA intends to issue regulations establishing standards for approved retailer training programs.



Tobacco Retailer Training Programs

For retailers who wish to implement training programs, the guidance explains:

- The civil money penalties that may be assessed against retailers for violations of restrictions under section 906(d) of the FD&C Act pertaining to restrictions on the sale and distribution of a tobacco product, including access, promotion and advertising restrictions
- How the penalty structure differs for retailers with and without approved training programs
- Definitions
- Recommendations for elements to be included in a retailer training program
- Recommended hiring and management practices



Tobacco Retailer Training Programs

Civil money penalty structure under the FD&C Act

Retailer with an approved training program, the amount of the civil penalty shall not exceed:

First violation, \$0.00 together with the issuance of a warning letter to the retailer

Second violation within a 12-month period, \$250

Third violation within a 24-month period, \$500

Fourth violation within a 24-month period, \$2,000

Fifth violation within a 36-month period, \$5,000

Sixth or subsequent violation within a 48-month period, \$10,000 as determined by the Secretary on a case-by-case basis.



Tobacco Retailer Training Programs

Civil money penalty structure under the FD&C Act
Retailer that does not have an approved training program,
the amount of the civil penalty shall not exceed:

First violation, \$250

Second violation within a 12-month period, \$500

Third violation within a 24-month period, \$1,000

Fourth violation within a 24-month period, \$2,000

Fifth violation within a 36-month period, \$5,000

Sixth or subsequent violation within a 48-month period, \$10,000 as determined by the Secretary on a case-by-case basis.

Tobacco Retailer Training Programs

An effective retailer training program should ensure that employees:

- (1) understand the tobacco access, advertising, and promotion restrictions of the Tobacco Control Act and implementing regulations;
- (2) verify that customers are of the legal age to purchase cigarettes and smokeless tobacco; and
- (3) successfully refuse purchase attempts by underage buyers.



Tobacco Retailer Training Programs

Recommended elements for retailer training program

- Applicable Laws and Penalties
- Health Effects of Youth Tobacco Use
- Written Company Policies Against Sales to Minors
- Comprehensive Description of Tobacco Products Covered by Laws Prohibiting the Sale of Tobacco Products to Youth
- Age Verification Requirements
- The Right to Refuse Sales When Acting in Good Faith
- Methods for Ensuring and Documenting that Employees Have the Knowledge Required to Comply with Laws Restricting the Access to, and Advertising and Promotion of, Tobacco Products



Tobacco Retailer Training Programs

Questions





Retailer Education Campaign

Campaign to educate retailers and raise awareness about tobacco product regulations designed to protect kids from the dangers of tobacco use and its negative health impacts.

www.fda.gov/breakthechain



Contact Information

- Mailing Address: Center for Tobacco Products, 9200 Corporate Blvd, Rockville, MD 20850
- Main Phone Number: 1-877-CTP-1373
- For General Consumer Inquiries: AskCTP@fda.hhs.gov
- For Media: 1-877.CTP.1373, option 2. Your call will be routed immediately
- For Tobacco Industry Questions: TobaccoIndustryQuestions@fda.hhs.gov
- For Small Business Industry Questions: smallbiz.tobacco@fda.hhs.gov
- To contact the [Ombudsman](#) about complaints and disputes, please email Les.Weinstein@fda.hhs.gov or call 301-796-9239.