

Analysis of the Family Smoking Prevention and Tobacco Control Act

Public Law 111-31

Food Marketing Institute

November 18, 2009

I. Overview

The President, on June 22, 2009, signed the Family Smoking Prevention and Tobacco Control Act (the “Tobacco Act”)¹ that addresses the 2000 United States Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corp.* In that case, the Supreme Court decided that the Federal Food, Drug & Cosmetic Act (the “FD&C Act”) did not give the U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products.

The Tobacco Act adds a new chapter to the FD&C Act that grants FDA the authority to regulate the sale, manufacture and marketing of tobacco and tobacco products. The term “tobacco product” means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product, including among other products, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Health and Human Services Secretary can include other tobacco products (e.g., cigars) within this law, by regulation.

Under its newly granted authority, FDA has created the “Center for Tobacco Products” which will oversee and implement the new law. Newly-appointed director Dr. Lawrence Deyton, M.D. will start with a \$5 million budget from fiscal year 2009. Future funding for the Center will come from user fees paid by manufacturers and importers of tobacco products.

As amended, the FD&C Act sets a new standard for the regulation of tobacco: the “appropriate protection of public health” standard. FDA does not have the authority – a power retained by Congress – to completely ban nicotine. FDA can, however, reduce nicotine levels in tobacco products.

The new law includes important deadlines and milestones, such as the following:

September 22, 2009 Cigarettes may not have candy, fruit, or spice flavors as their characterizing flavors; menthol cigarettes are not affected by the ban.

January 2010 Tobacco manufacturers and importers must submit information to FDA about ingredients and additives in tobacco products.

180 Days The Tobacco Act requires FDA to reissue, as a final rule, the original 1996 regulation with certain changes prescribed in the Tobacco Act (“1996 Tobacco Regulation”)² in 180 days or more after June 22, 2009.

June 22, 2010 The 1996 regulation will become effective on June 22, 2010.

July 2010 Tobacco manufacturers may no longer use the terms “light,” “low” or “mild” on tobacco products without an FDA order in effect, unless the product was marketed in commerce prior to February 2007 (see below).

July 2010 Stronger new warning labels for smokeless tobacco products will apply.

September 2011 Regulations will be issued regarding retail sale or distribution of tobacco through means other than direct, face-to-face exchange.

March 2012 Regulations will be issued regarding promotion or marketing of tobacco products sold through means other than direct, face-to-face exchange.

October 2012 Warning labels for cigarettes will be revised and strengthened.

II Retailer-Specific Provisions

The Tobacco Act includes important provisions relevant to retailers. As discussed more fully below, retailers are prohibited from selling tobacco products to minors and must train their employees in this regard. New federal penalties will apply to retailers who sell tobacco products to minors; stiffer penalties apply to retailers

¹ To view a copy of the Tobacco Act: <http://www.govtrack.us/congress/billtext.xpd?bill=h111-1256>

² [INSERT LINK TO 1996 TOBACCO REGULATION]

without the proper employee training programs. Retailers should also be mindful of new labeling, marketing and advertising restrictions.

A. General Sales Restrictions

Both the Tobacco Act and the 1996 Regulation³ (which will become effective on June 22, 2010) prohibit the sale of tobacco products from vending machines or self-service displays except in adult-only facilities, which are defined as facilities that prohibit entry of persons under 18. No retailer, manufacturer or distributor may provide free samples of cigarettes, smokeless tobacco⁴ or other tobacco products. In addition, retailers may not sell packages of cigarettes containing fewer than 20 cigarettes.⁵

B. Sales to Minors

Retailers must continue to prohibit the sale of tobacco to persons under the age of 18. As required by the Tobacco Act, an expert panel will be convened to conduct a study on the public health implications of raising the minimum age to purchase tobacco products. The results of this study are to be submitted to Congress.

C. Retailer Training

Retailers must implement written policies and procedures that include employee training procedures and disciplinary actions with regard to sales of tobacco products to minors. The employee-training program must be approved by FDA and must include (1) procedures to verify picture identification or the use of an electronic scanning device; (2) informing employees of all applicable laws; and (3) establishing disciplinary sanctions for employee noncompliance.

The Tobacco Act defines the term “approved training program” as “a training program that complies with standards developed by the FDA for such programs.” At this point, however, no such FDA standards or procedures have been developed, other than the three items listed in the previous paragraph and no date certain has been given for when they will be.

Nonetheless, FMI serves on the Board of Directors for the “We Card” Training and Education Program (www.wecard.org). We Card has trained hundreds of thousands of retail employees to successfully prevent underage tobacco sales and properly comply with laws and regulations. FMI will seek to ensure that the We Card program qualifies as an “approved training program.”

D. Penalty Provisions

1. “Safe Harbor” and Monetary Penalties for Sales to Minor Violations

The Tobacco Act establishes a “safe harbor” on a first violation for retailers that sell tobacco to minors if the retailer has the correct procedures in place (including an “approved training program”) and the retailer relies in good faith on a government-issued picture identification, even if the identification is false. For a second and third violation, however, monetary penalties will be issued to the retailer, but at a lesser amount than those retailers without an approved training program. Once a retailer with an FDA approved training program in place reaches a fourth violation in a 24 month period, the reduced monetary phase ends and the penalty schedule intersects with the fine provisions for retailers without an approved training program.. (See the chart below.)

³ The 1996 Regulation as modified by the Tobacco Act – the original statute and preamble no longer has binding effect.

⁴ Free samples of smokeless tobacco may be distributed in an adult-only facility In addition; states or local government may prohibit or otherwise restrict the distribution of free samples of smokeless tobacco in adult-only facilities.

⁵ According to FDA, 20 was selected because most U.S. cigarette packs contain 20 cigarettes, and this is intended to preclude firms from manufacturing packages that contain less, as these packs are easier to conceal, and are less expensive than full-size packs and therefore may be more appealing to children.

Penalty Schedule		
Violations	Retailers with Approved Training	Retailers without Approved Training
First	Warning Letter – no monetary penalty	\$250
Second within 12 months	\$250	\$500
Third within 24 months	\$500	\$1,000
Fourth within 24 months	\$2,000	\$2,000
Fifth within 36 months	\$5,000	\$5,000
Sixth within 48 months	\$10,000	\$10,000

2. “No Tobacco Sale” Order and Request for Hearing for Sales to Minors Violations

If the Secretary finds that a person has committed repeated violations⁶ of sales to minors (section 906d) at a particular retail outlet, then a no-tobacco-sale order can be placed on that person prohibiting the sale of tobacco products in that outlet. Repeated violations are defined as five violations in a 36 month period at the same retail outlet. Before issuing a violation, FDA will provide retailers with notice by certified or registered mail or personal delivery that includes information related to procedures for a hearing. A retailer may request a hearing by telephone or at the nearest regional or field office of the FDA.

3. Coordination with States

The Tobacco Act directs FDA to consider the amount of any penalties a retailer pays to a state for the same violation of the Tobacco Act and directs FDA to mitigate civil penalties accordingly.

IV. Labeling, Marketing and Advertising

A. Labeling

By July 2010, warning labels for *smokeless tobacco* products will be revised and strengthened. By October 2012, warning labels for *cigarettes* will be revised and strengthened. Warnings for cigarettes will comprise the top 50 percent of the front and rear panels of the cigarette package. The word, “warning” must appear in all capital letters. One of the following labels must appear on each package:

- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.
- WARNING: Cigarettes are addictive.

Additionally, specific warnings must appear on the labels of smokeless tobacco, (e.g., “WARNING: This product can cause mouth cancer.”) FDA will issue regulations requiring graphics on labels depicting the negative health consequences of smoking. Once established, FDA will communicate with industry and the public about implementation.

⁶ The Tobacco Act directs FDA to issue guidance in more precisely defining the term, “repeated violation.”

B. Marketing

1. “Light” Cigarettes and Premarket Review

The Tobacco Act imposes new requirements on “modified risk” tobacco products,⁷ such as cigarettes that are marketed as “light,” “low” or “mild.” Specifically, as of July 2010, all new tobacco products marketed with these terms must undergo premarket review and obtain FDA approval before they are marketed. A new tobacco product is one that was not commercially marketed or test marketed as of February 15, 2007. All tobacco products that were commercially marketed or test marketed, in the United States before that date may continue to be marketed without premarket approval, but must comply with all provisions of the Tobacco Act. The premarket review requirement applies to all tobacco products (not just, “modified risk”) that were marketed prior to February 15, 2007 but that are subsequently modified in specified ways including in terms of design, ingredients or nicotine content.

2. Combination Products

Section 201(rr)(4) of the FD&C Act as amended by the Tobacco Law prohibits the marketing of tobacco products in combination with any other article or product regulated under the FD&C Act (including drugs, biologics, food, cosmetics, medical devices or dietary supplements). In September 2009, FDA issued draft guidance⁸ interpreting the new statutory provision entitled, “The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act (FDCA).”⁹ According to the draft guidance, FDA interprets the new provision to prohibit the following:

- a coupon for a 50 cent discount on a specifically identified mouthwash is offered contingent upon the purchase of a pack of cigarettes;
- compressed or powdered tobacco is added to candy or gum (which are foods under the FD&C Act) and the candy or gum is identified as containing a tobacco product; and,
- a tobacco product and a non-tobacco product regulated under the FD&C Act packaged together in a single package or as a unit, such as a pack of cigarettes shrink-wrapped or sold in a box, bag, or other container with a bottle of mouthwash.

The same guidance also states FDA’s belief that the following activities would not be prohibited:

- a tobacco product and a non-tobacco product regulated under the FD&C Act are advertised on the same store sign or in the same store circular or advertised in the same place; or,
- two or more tobacco products are packaged together in a single package or as a unit.

Comments should be filed with FDA on this guidance by January 4, 2010. See:

www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm184283.htm

C. Advertising

The Tobacco Act imposes new restrictions on tobacco product advertising. For example, the new law prohibits tobacco companies from sponsoring sporting events. Moreover, tobacco products may not be advertised within 1,000 feet of a school or public playground.¹⁰

The Tobacco Act also relegates tobacco product advertising to so-called, “tombstone advertising” (black and white) and states that all advertising must contain a warning statement, such as those required

⁷ A “modified risk” tobacco product is one that is sold or distributed for sale to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

⁸ See: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm184283.htm>

⁹ This draft guidance, when finalized, will represent the FDA’s current thinking on this topic. According to FDA, an alternative approach may be used if the approach satisfies the requirements of the applicable statutes and regulations. Alternative approaches may be discussed with FDA staff.

¹⁰ Neither the Tobacco Act nor the 1996 Regulation addresses line-of-sight implications for retailers near schools and playgrounds other than the aforementioned 1,000 foot stipulation.

on tobacco product packages (see “Labeling,” above). Specific provisions regulate advertising in newsprint and on matchbooks.

D. Retailer Violations of Labeling, Marketing and Advertising Provisions

A retailer is responsible for advertising if it is displayed in a location open to the public. However, retailers will not be held in violation of the advertising or packaging requirements if the ad or package (1) contains a warning label; (2) is supplied to the retailer by a licensed or permit-holding tobacco product manufacturer, importer, or distributor; and (3) has not been altered by the retailer in a manner that is specified by law.

V. Flavored Tobacco Products

Effective September 22, 2009, cigarettes that contain certain characterizing flavors are considered adulterated. Specifically, section 907(a)(1)(A) of the FD&C Act, as amended by the Tobacco Act, establishes a tobacco product standard special rule for cigarettes that states in part:

...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.

This standard applies to all tobacco products that meet the definition of a “cigarette” in section 900(3) of the FD&C Act even if they are not labeled as “cigarettes” or are labeled as cigars or as some other product.¹¹

Currently, menthol is not included in this ban. However, the Tobacco Products Scientific Advisory Committee, which advises the FDA Commissioner in discharging responsibilities as they relate to the regulation of tobacco products, will submit a recommendation on the impact of the use of menthol in cigarettes on the public health. Adulterated products sold or held for sale in the United States may be subject to seizure under section 304 of the Tobacco Act. In addition, manufacturers, distributors, and retailers may be subject to injunctions, civil money penalties, and criminal prosecution for violating the requirements of the Tobacco Act.

VI. Preservation of State and Local Authority

In addition to the provisions outlined in the federal law, states, localities, and tribal governments are permitted to impose requirements that are in addition to or more stringent than FDA requirements. For example, states may:

- impose specific bans or restrictions on the time, place, and manner – but not the content – of cigarette advertising;
- may prohibit or restrict the distribution or free samples of smokeless tobacco in any location; and,
- may tax tobacco products.

The Tobacco Act directs FDA to coordinate with the states in enforcing the provisions of the Tobacco Act.

VII. Regulatory Proceedings

Much of the new law will require implementation through rulemaking as an initial matter. FDA has established a public docket to obtain comments on the overall implementation of the Tobacco Act. Comments should be submitted by December 28, 2009 to <http://www.regulations.gov>. To view submitted comments:

<http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2009-N-0294>

In addition, FDA is also seeking public comment on draft guidance entitled, “The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act.” Comments should be filed with FDA on this guidance by January 4, 2010. See: www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm184283.htm

¹¹ See, “Letter to Industry on Cigarettes Containing Certain Characterizing Flavors” at: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm182186.htm>

VIII. Summary

The Tobacco Law will impose new requirements on those who manufacture and import tobacco products, as well as those who sell or distribute them. The most important provisions for retailers concern sales to minors and employee training. In addition, retailers should be aware of new requirements related to labeling, marketing and advertising tobacco products.

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