

# **THE NEW FDA TOBACCO RULE**

**[Effective June 22, 2010]**

The FDA tobacco legislation (signed into law by President Obama on June 22, 2009) calls for the implementation of virtually all of the FDA Final Rule relating to cigarettes and smokeless tobacco products that was promulgated and partially implemented in 1996 (before the U.S. Supreme Court struck it down, ruling that FDA could not implement the Rule until Congress passed legislation specifically authorizing FDA to do so). The following is the Final Rule text, as amended by the new FDA tobacco law, as renumbered and published by FDA on March 19, 2010. Except as noted below, the entire rule is effective as of June 22, 2010.<sup>1</sup>

## **SUBCHAPTER K--TOBACCO PRODUCTS**

### **PART 1140--CIGARETTES AND SMOKELESS TOBACCO**

#### **Subpart A--General Provisions**

##### ***Sec. 1140.1 Scope.***

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

##### ***Sec. 1140.2 Purpose.***

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

##### ***Sec. 1140.3 Definitions.***

(a) Cigarette. (1) Means a product that:

(i) Is a tobacco product; and

(ii) Meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(b) Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

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<sup>1</sup> The new FDA tobacco law gives FDA full authority to amend, extend or supplement this new Rule, by promulgating a proposed rule that makes the changes. It also directs FDA to ensure that the provisions relating to the retail sale of tobacco products in this Rule (or in the rest of the new FDA tobacco law and any related new rules or regulations) are enforced "with respect to the United States and Indian Tribes" (i.e., reaching all tobacco product retailers in the USA, wherever located and however owned). For more on this new Final Rule and FDA's implementation of the Rule, see the FDA website at the following link: <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm>.

(c) Distributor means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) Manufacturer means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) Nicotine means the chemical substance named 3-(1-Methyl-2- pyrrolidinyl)pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

(f) Package means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.

(g) Point of sale means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) Retailer means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) Smokeless tobacco means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

## **Subpart B--Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age**

### ***Sec. 1140.10 General responsibilities of manufacturers, distributors, and retailers.***

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

### ***Sec. 1140.12 Additional responsibilities of manufacturers.***

In addition to the other responsibilities under this part, each manufacturer shall 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 requirements under this part.

### ***Sec. 1140.14 Additional responsibilities of retailers.***

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in Sec. 1140.16(c)(2)(i) and in paragraph (b)(2) of this section, 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;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in Sec. 1140.16(c)(2)(ii), 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);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in Sec. 1140.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(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 with the requirements under this part.

***Sec. 1140.16 Conditions of manufacture, sale, and distribution.***

(a) *Restriction on product names.* 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.<sup>2</sup>

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, 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.

(c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d)(1) *[Free Samples.]* Except as provided in paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(2)(i) Paragraph (d)(1) of this section does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

(ii) Paragraph (d)(2) of this section does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

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<sup>2</sup> FDA has said it will postpone enforcing this provision until concerns are resolved about its scope. See: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm210762.htm>.

(iii) For purposes of paragraph (d) of this section, the term "qualified adult-only facility" means a facility or restricted area that:

(A) Requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

(B) Does not sell, serve, or distribute alcohol;

(C) Is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

(D) Is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this paragraph (d)(2) of this section;

(E) Is enclosed by a barrier that:

(1) Is constructed of, or covered with, an opaque material (except for entrances and exits);

(2) Extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

(3) Prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

(F) Does not display on its exterior:

(1) Any tobacco product advertising;

(2) A brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

(3) Any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate Sec. 1140.34(c).

(iv) Distribution of samples of smokeless tobacco under paragraph (d)(2) of this section permitted to be taken out of the qualified adult-only facility shall be limited to one package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed eight individual portions, and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the amounts in this paragraph (d)(2)(iv) are limited to one such package per adult consumer per day.

(3) Notwithstanding paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco:

(i) To a sports team or entertainment group; or

(ii) At any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by paragraph (d)(3) of this section.

(4) The Secretary shall implement a program to ensure compliance with paragraph (d) of this section and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

(5) Nothing in paragraph (d) of this section shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.

(e) Restrictions on labels, labeling, and advertising. 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 with subpart D of this part, and other applicable requirements.

### **Subpart C--[Reserved]**

### **Subpart D--Labeling and Advertising**

#### ***Sec. 1140.30 Scope of permissible forms of labeling and advertising.***

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, 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.

(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 paragraph (a)(1) of this section, 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. The manufacturer, distributor, or retailer shall send this notice to the Office of Compliance, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850-3229.

(b) [Reserved]<sup>3</sup>

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

#### ***Sec. 1140.32 Format and content requirements for labeling and advertising.***

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.<sup>4</sup>

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<sup>3</sup> This subsection originally called for a total ban on outdoor cigarette or smokeless ads within 1000 feet of schools or playgrounds. But the new FDA tobacco law directed FDA to modify the subsection prior to the publication of the Final Rule if FDA determined that any modifications were appropriate in light of governing case law regarding the First Amendment and permissible restrictions on commercial speech. On March 19, 2010, FDA published the Final Rule without any such subsection, at all; but FDA issued a related notice and request for comments re possible future restrictions on outdoor ads. See <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm>.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

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

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

***Sec. 1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.***

(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.

(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.

(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. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing 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.

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<sup>4</sup> A District Court in Kentucky has ruled that this provision violates the First Amendment (but could be made compliant with relatively minor modifications). FDA is appealing that ruling, but will not be enforcing this provision until the legal issues are resolved. For more information, see the FDA website at: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm210762.htm>.