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Effective: June 22, 2010

Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)Subchapter K. Tobacco Products (Refs & Annos)Part 1140. Cigarettes and Smokeless Tobacco (Refs & Annos)

Subpart B. Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

→ § 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.

(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) 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

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In order to be considered an establishment that can use vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays, no person under the age of 18 may be present, or permitted to enter, at any time (emphasis added). For example, if you own a bar that is also connected to a restaurant, and people younger than 18 years of age can eat at the restaurant, then your bar does not qualify for the exception even if people younger than 18 years of age cannot go to the bar. The exception is very narrow; it applies to places that are entirely off-limits to people younger than 18 years of age at all times.

There are limits to the exception. For example, if you own a factory and there are 10 buildings on the factory grounds, but you only want to put a cigarette vending machine in one building, it would not be reasonable to require you to make sure that people younger than 18 years of age are not permitted to enter in all 10 buildings. You would only be expected to keep people younger than 18 years of age from being present in or entering the building that contains the vending machine. Similarly, you are not expected to be responsible for things outside your retail establishment. For example, if you rent a store on the ground floor of a public building and the main entrance of the building is separate from the entrance to your store, you would only be expected to keep people younger than 18 years of age from being present or entering your store in order to qualify for the exception. You would not have to try to keep them from entering the rest of the building.

Can I let people younger than 18 years of age into my facility on special occasions?

FDA recognizes that some facilities, such as clubs or recreation halls, might be “off limits” to people younger than 18 years of age most of the time, but that they are occasionally rented for parties or other social events where people younger than 18 years of age may be present. Nevertheless, if the facility has a vending machine or self-service display for cigarettes or smokeless tobacco, no one younger than 18 years of age can be present or be permitted in the facility at any time, even on special occasions. If you own a facility that people younger than 18 years of age are permitted to enter, you will not qualify for this exemption.

Who is responsible for a vending machine in a facility?

If you have a vending machine in your facility, you are responsible for ensuring that no one younger than 18 years of age is present or permitted to enter at any time, whether you own or rent, or otherwise operate the facility. These regulations consider you to be a retailer for the purposes of this exception. In cases where someone other than the retailer owns the vending machine, you are responsible.

FDA recognizes that the person who owns a facility might not be the same person who owns a vending machine in the facility. Nevertheless, as the person who owns or operates the facility in which the vending machine is located, you are responsible. You do not have to own the vending machine in order to be held responsible.

What is a “self-service display” under the regulations?

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A self-service display is any item that permits a consumer to remove a cigarette or smokeless tobacco product without the retailer's direct assistance. Self-service displays, which also may be referred to as "merchandisers," come in many different shapes and sizes, ranging from free-standing, multi-shelf kiosks to small display stands that are placed next to a cash register. Regardless of the type or size, a self-service display is not permitted in any pharmacy, convenience store, grocery store, gas station, restaurant, or any other place where anyone younger than 18 years of age can enter or is present at any time. So, in most cases, if you are a retailer, you cannot use self-service displays and vending machines in your store.

Can I move a self-service display or vending machine to an area where I can supervise it, without having to get rid of the display or vending machine?

No. The regulation prohibits all "impersonal" modes of sale for cigarettes and smokeless tobacco products. Supervising a display or vending machine, using electronic locks, remote operating mechanisms, or taking other actions that continue to give customers direct access to cigarettes or smokeless tobacco products is not permitted because these would be considered "impersonal" modes of sale. These indirect forms of control over displays and vending machines are often ineffective when it comes to preventing children and adolescents from helping themselves to cigarettes or smokeless tobacco.

The regulations require retailers to remove self-service displays and vending machines or to move them to a place where customers are not able to help themselves to the product. If you are a retailer, the regulations require you to hand the product to the customer in a direct, face-to-face exchange. For example, if you have a small countertop display that holds cigarette packs, you cannot keep that display on the counter if customers can help themselves to the cigarettes. It does not matter whether you can see them choose the cigarettes or whether they have to "ask permission" to buy them if the customer can take the cigarettes without any action on your part.

In contrast, if you move the countertop display behind the counter to an area where customers are not permitted to enter, you can keep the display. By moving the display out of the customer's reach, you have eliminated the "self-service" aspect of the display.

§1140.16(d)--Free samples

No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes.

A manufacturer, distributor, or retailer may only distribute or cause to be distributed free samples of smokeless tobacco in a "qualified adult-only facility." Under the regulations, the term "qualified adult-only facility" means a facility or restricted area that:

- (1) 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 a government-issued identification showing a photograph and at least 18 years of age (state law may be older);
- (2) does not sell, serve, or distribute alcohol;