U.S. Food and Drug Administration

Tobacco Products

Draft Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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Draft Guidance for Industry(1) Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

This draft guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementin this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This draft guidance is intended to assist manufacturers, distributors, retailers, and others who sell cigarettes and/or smokeless tobacco in understanding the final Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents**(2)** and to explain what you should do in order to comply with the regulations. The document explains among other things:

- Access, which consists largely of requirements concerning the sale of cigarettes and smokeless tobacco;
- Advertising, which includes requirements for product labels, labeling, and advertising;
- Who is subject to the regulation;
- What products are subject to the regulation;
- Prohibition on the sale and distribution of tobacco products to persons younger than 18 years of age

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FFDCA) and providing FDA with the authority to regulate tobacco products. Section 102 of the Tobacco Control Act require FDA to publish final regulations regarding cigarettes and smokeless tobacco which are identical in their provisions to the regulations promulgated by FDA in 1996 (1996 final regulations)**(3)**, with certain specified exceptions.

In enacting the Tobacco Control Act, Congress made extensive legislative findings regarding the lethal and addictive nature of tobacco products, including that tobacco use is the foremost preventable cause of premature death in the United States. Tobacco use causes approximately 440,000 deaths each year**(4)**. Moreover, advertising, marketing, and promotion of tobacco products have been "especially directed to attrac young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." Tobacco Control Act § 2 (15). The use of tobacco products is a "pediatric disease" and an effective program to address this disease must include restrictions on youth access and restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people. Tobacco Control Act §§ 2(1), (25) (26), (30)-(32).

As Congress recognized, the 1996 final regulations were "the longest rulemaking proceeding in FDA history," with 700,000 comments received in the course of the rulemaking**(5)**. Both the 1996 final regulations and the 1995 proposed regulations included extensive discussions of the scientific information available at the time and the final regulations included FDA's responses to more than 700,000 comments on the proposed regulations.

III. DISCUSSION

On March 19, 2010, FDA published its final regulations entitled Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, at Title 21, Code of Federal Regulations (C.F.R.), Part 1140**(6)**. Consistent with the requirements of section 102 of the Tobacco Control Act, these regulations prohibit the sale of cigarettes and smokeless tobacco to any person younger than 18 years of age and impose restrictions on marketing, labeling, and advertising of cigarettes and

smokeless tobacco. The regulations require retailers to verify a purchaser's age by photographic identification prohibit free samples of cigarettes and restrict distribution of free samples of smokeless tobacco to qualified adult-only facilities as defined in the regulation; prohibit the sale of cigarettes and smokeless tobacco product through vending machines and self-service displays, except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; and prohibit sponsorship of sporting and other events, teams, and entries in those events in the brand name of any cigarette or smokeless tobacco product.

*Section 1140.32(a) of this new regulation establishes format and content requirements for labeling and advertising to allow only black text on a white background, with limited exceptions. The court in Commonwealth Brands, Inc. v. United States (No. 1:09-CV-117-M, W.D. Ky. Jan. 4, 2010), permanently enjoined FDA from enforcing section 21 C.F.R. 1140.32(a) against the parties to the case in any jurisdiction ir the United States. On March 8, 2010, the government filed an appeal from that order. As announced in the guidance document published on May 7, 2010, FDA intends to exercise its enforcement discretion concerning 21 C.F.R. 1140.32(a) not to commence enforcement actions under this provision during the pendency of the litigation irrespective of whether the entity is a party to the pending lawsuit or located in the Western District of Kentucky**(7)**. The agency will update this guidance following a final resolution of this matter.*

What and Who are Subject to the Regulations?

The Tobacco Control Act amends the FFDCA by providing FDA with the authority to regulate tobacco products FDA has promulgated 21 C.F.R. Part 1140 to establish regulations to prohibit the sale of cigarettes and smokeless tobacco to any person under age 18 and restrictions on marketing, labeling, and advertising of cigarettes and smokeless tobacco products.

The FFDCA defines a "tobacco product" as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 201(rr) of the FFDCA. It does not mean an article that is a drug under section 201(g)(1) of the FFDCA a device under section 201(h) of the FFDCA, or a combination product under section 503(g) of the FFDCA.

The regulations cover two types of tobacco products: cigarettes and smokeless tobacco. Smokeless tobacco means any tobacco product that consists of cut up, ground, powdered, or leaf tobacco that is intended to be placed in the nose or mouth (section 900(18) of the FFDCA), and includes moist snuff, snus, dry snuff, nasal snuff, loose leaf chewing tobacco, plug chewing tobacco, and twist chewing tobacco. Currently, the regulation do not apply to cigars, little cigars or pipe tobacco.

The regulations apply to:

- manufacturers,
- distributors, and
- retailers

who manufacture, distribute, or sell cigarettes and smokeless tobacco.

This guidance describes the products and persons that are covered by the regulations in greater detail in the discussion of the "Definitions" section below.

Do Other Regulatory Requirements Apply to Me?

The Tobacco Control Act and other FDA regulations may impose requirements on you in addition to those contained in the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents. For example, section 904 of the FFDCA, as amended by the Tobacco Contro Act, requires tobacco product manufacturers to submit tobacco product ingredient information to FDA. The agency has issued several guidance documents to assist regulated industry in complying with the provisions o the Tobacco Control Act. These guidances are posted on our Web site at:

http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm[4].

Similarly, the Federal Cigarette Labeling and Advertising Act (P.L. 89-92; 79 Stat. 282) and the Comprehensive Smokeless Tobacco Health Education Act (P.L. 99-252; 100 Stat. 34) require companies to place rotational health warnings on cigarette and smokeless tobacco packages and in advertisements. The Tobacco Control Act amends each of these laws to require new, larger, and more prominent warnings and to give FDA administrative and enforcement responsibilities for the warnings.

If you fail to comply with a regulatory requirement that applies to you, the cigarettes or smokeless tobacco that you manufacture, distribute, or sell may be considered adulterated or misbranded. You may then be

subject to regulatory action, including warning letters, injunctions, seizures, civil money penalties, prosecution, and no-tobacco-sale orders by FDA.

Please note that other federal, state, or local laws may affect you as well. For example, your state or local government may require persons who sell cigarettes or smokeless tobacco to be a certain age or require retailers to obtain licenses to sell these products. To determine whether any additional federal, state or local requirements apply to you, we suggest that you contact your state or local health departments and law enforcement agencies.

Regulatory Requirements Specific to the Sale and Distribution of Cigarettes and Smokeless Tobacco

Overview

The regulations at 21 C.F.R. Part 1140 are designed to:

- reduce access to cigarettes and smokeless tobacco by persons under age 18, and
- reduce the appeal of such products to persons under age 18, through restrictions on marketing, labeling and advertising.

In 1996, FDA issued these regulations after conducting an extensive review and analysis of the scientific and medical literature on cigarette and smokeless tobacco use by children and adolescents and examining over 700,000 comments that were submitted on the proposed regulations. Many comments contained helpful information that enabled FDA to revise the proposed regulations and to create a practical regulatory system for these products.

The regulations are not designed or intended to prevent sales to adults or interfere with a manufacturers', distributors', or retailers' ability to communicate truthful and non-misleading information to adult consumers.The regulations are divided into two main components: (1) access provisions, which consist largel of restrictions on the sale of cigarettes and smokeless tobacco, and (2) restrictions on advertising, marketing, and promotion of cigarettes and smokeless tobacco products. To help you understand these requirements, thi guidance examines each section in the order in which it appears in 21 C.F.R. Part 1140 and provides answers to several questions relating to each section of these requirements. [The complete text for 21 C.F.R. Part 114 is attached in Appendix A.]

Section-by-Section Analysis of 21 C.F.R. Part 1140

A. Subpart A--General Provisions

Subpart A consists of 3 sections: (1) §1140.1, "Scope," which explains the scope of the regulations and the possible consequences of a failure to comply with any applicable provision in Part 1140, (2) §1140.2, "Purpose," which states the regulations' purpose, and (3) §1140.3, "Definitions," which defines certain terms used in Part 1140. Subpart A does not itself impose any obligations on manufacturers, distributors, or retailers, but instead provides helpful background on the regulations, particularly with respect to the definitions applicable to the regulations.

1. §1140.1--Scope

§ 1140.1 explains that the regulations establish restrictions, under the FFDCA, on the sale, distribution, and use of cigarettes and smokeless tobacco. It also explains that the failure to comply with any applicable provision in 21 C.F.R. Part 1140 may render a cigarette or smokeless tobacco product "misbranded" under the FFDCA. Once a product is considered misbranded, FDA can take enforcement action against the party who causes the misbranding or any party who further distributes the misbranded product. Misbranding of a tobacco product is prohibited under section 301(b) of the FFDCA. The introduction, or delivery for introductior into interstate commerce of any misbranded tobacco product is also prohibited under section 301(a) of the FFDCA.

2. §1140.2--Purpose

§ 1140.2 explains that the restrictions on the sale and distribution of cigarettes and smokeless tobacco were established in order to reduce the number of children and adolescents who use these products and to reduce life-threatening consequences associated with tobacco use.

When FDA began drafting the regulations in 1995, cigarette sales to children were illegal in all states, yet published reports in medical journals estimated that children bought millions of packs of cigarettes. Other information available to FDA indicated that most cigarette smokers started before they reached 18, so that if person didn't start smoking by the time he or she reached 18, it would be unlikely that he or she would ever

start smoking. By reducing the number of children who start smoking, the regulations could lower the death rate attributed to cigarettes (approximately 440,000 Americans annually).

3. §1140.3--Definitions

The definitions are important, because they describe the types of products that are regulated, and the person who are subject to regulations.

What products are subject to regulation under 21 C.F.R. Part 1140?

The regulations apply to some, but not all, tobacco products. Specifically, the regulations apply to cigarettes and smokeless tobacco. These items are defined as:

- The term "cigarette" is defined by section 900(3) of the FFDCA, as amended by the Tobacco Control Act to
  (1) "[Mean] 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."
  Section 3(1) of the Federal Cigarette Labeling and Advertising Act (FCLAA) defines the term "cigarette" to mean –
  (A) "any roll of tobacco wrapped in paper or in any substance not containing tobacco, and
  (B) any roll of tobacco wrapped in any substance containing tobacco 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 described in subparagraph (A)."
  A cigarette that is subject to these regulations must contain tobacco. A tobacco product may also meet the definition of a "cigarette" if it contains "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 t be offered to, or purchased by, consumers as a cigarette or as roll-your-own-tobacco."**(8)** Accordingly, tobacco product that meets the definition of a "cigarette," even if it is not labeled as a "cigarette" or is labeled as a cigar or as some other product, may be subject to the regulations**(9)**. In other words, a product is a "cigarette" despite any other names that may be used to describe it, if it appears to be a cigarette, contains a certain kind of tobacco in its filler, or the packaging and labeling indicates that it is likely offered to a consumer or bought by the consumer as a cigarette.
  Currently, other tobacco products, notably cigars, little cigars, and pipe tobacco, which do not meet the definition of cigarettes, are not subject to these regulations.
- The term **"cigarette tobacco"** is defined by section 900(4) of the FFDCA, as amended by the Tobacco Control Act, as "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 als apply to cigarette tobacco." Under the statute, cigarette tobacco is treated the same as cigarettes. Thus roll-your-own cigarette tobacco is subject to the restrictions in these regulations.
- The term **"smokeless tobacco"** is defined by section 900(18) of the FFDCA, as amended by the Tobacco Control Act, as "any product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity."
  Section 4408 of the FCLAA defines the term "smokeless tobacco" to mean –
  "any finely cut, ground, powered, or leaf tobacco that is intended to be placed in the oral cavity, including snuff, chewing tobacco, and plug tobacco."
  FDA notes that the definitions of "smokeless tobacco" in the FFDCA and the FCLAA are different in that the FFDCA definition includes its use in the oral or nasal cavity whereas the FCLAA defines the term as for use in the oral cavity. However, smokeless tobacco products meeting the definition under the Tobacco Control Act are subject to the restrictions in these regulations. There are many types of smokeless tobacco. The principal names for the various types of tobacco are: moist snuff, snus, dry snuff, loose leaf chewing tobacco, plug chewing tobacco, and twist chewing tobacco.

Please note that the regulations do not make any distinction for foreign cigarettes or smokeless tobacco products that are imported into the United States. If you import, distribute, or offer foreign cigarettes or smokeless tobacco products for sale in the United States, you and your products must comply with these regulations.

Who is subject to regulation under 21 C.F.R. Part 1140?

The regulations apply to: (1) manufacturers; (2) distributors; and (3) retailers.

- **"Manufacturers"** include any person, "including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product."**(10)** For example, if you make cigarettes, you are a manufacturer under these regulations. Similarly, if you take finished cigarettes from Company A, remove the cigarettes from Company A's cartons, and place them in packages with your company's name (or any other name) on the package, you are a manufacturer because you repacked and relabeled the cigarettes, even though you didn't make the finished cigarettes themselves.
- **"Distributors"** include any person "who furthers the distribution of cigarettes or smokeless tobacco, *whether domestic or imported*, at any point from the original point of manufacture to the person who sells or distributes the product to individuals for personal consumption," but excludes common carriers (emphasis added).**(11)**
  Most distributors who are subject to regulation under 21 C.F.R. Part 1140 will be persons who run warehousing operations and distribute cigarettes or smokeless tobacco products to retailers.
  If you own a trucking firm and are contracted to transport cigarettes from a warehouse to a retailer, you are a "common carrier" and are exempt from these regulations even though you technically further the distribution of the tobacco product to the retailer.
  A distributor also includes any person who is the owner or consignee at the time of entry for a tobacco product that is imported into the United States. Persons that purchase bulk shipments of tobacco products from foreign countries and sell to manufacturers, distributors, or retailers are considered distributors, because they are furthering the distribution of cigarettes and smokeless tobacco, and are also subject to the regulations under 21 C.F.R. Part 1140.
- **"Retailers"** are persons who sell cigarettes or smokeless tobacco to individuals for personal consumption, or who operate a facility where vending machines or self-service displays are permitted under these regulations.**(12)** This definition applies regardless of the number of products sold or the price at which they are sold.
  For example, even if Store A generates most of its sales from selling food products, and cigarettes sales represents only a fraction of total sales, the store is a "retailer" subject to regulation under 21 C.F.R. Part 1140. The store will be a retailer regardless of whether it sells above cost, at cost, or below cost.
  Retailers also include persons who own facilities where vending machines that sell tobacco products or self-service displays (or merchandisers) of tobacco products are located, even if they technically do not own the vending machines or self-service displays themselves. The reason for including persons who own facilities where vending machines or self-service displays are located is described in more detail in the discussion for 21 CFR Part 1140.16 below.
  Note that the definitions of distributor, manufacturer, and retailer are not mutually exclusive. In other words, you can be a manufacturer, distributor, and a retailer if you engage in actions that fall within each of the definitions. For example, if you make finished cigarettes and sell them to individuals, you are a manufacturer (because you made the cigarettes) and a retailer (because you sold them to individuals)

The Tobacco Control Act does not apply to growers of tobacco, tobacco warehouses, and tobacco grower cooperatives. Section 901(c)(2) of the FFDCA, as amended by the Tobacco Control Act. A tobacco warehouse includes any person who removes foreign material from tobacco leaf through nothing other than a mechanical process; humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or de-stems, dries, and packs tobacco leaf for storage and shipment. However, the term tobacco warehouse does not include businesses that reconstitute tobacco leaves; are manufacturers, distributors or retailers of tobacco products; or apply any substances to the tobacco leaves other than water in the form of steam or mist. Section 900(21) of the FFDCA, as amended by the Tobacco Control Act. Accordingly, growers of tobacco, tobacco warehouses, and tobacco grower cooperatives are not subject to the requirements of 21 C.F.R. Part 1140.

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

Subpart B of the regulations contains the "access" restrictions. It consists of 4 sections: (1) §1140.10, "General responsibilities of manufacturers, distributors, and retailers," (2) §1140.12, "Additional responsibilities of manufacturers," (3) §1140.14, "Additional responsibilities of retailers," and (4) §1140.16, "Conditions of manufacture, sale and distribution." The sections in this subpart detail how you can distribute or sell cigarettes or smokeless tobacco and the locations at and the manner in which these products can be sold.

1. §1140.10--General Responsibilities of Manufacturers, Distributors and Retailers

The regulations at §1140.10 state that each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, distributes, labels, packages, advertises, sells, or otherwise holds for sale comply with all applicable regulatory requirements.

This section is intended to remind parties that they must meet their regulatory obligations under 21 C.F.R. Part 1140. You should ensure that you and your cigarettes and smokeless tobacco products are in compliance with those regulatory requirements that apply to you and your products. Note that you also may be subject to regulatory action if you assist another person in violating these regulations.

In situations where you know that another person is violating the regulations, FDA recommends that you notify the party responsible for the violation. For example, some possible options for you to consider may include:

- removing the violative product or item, e.g., cigarette or smokeless tobacco product, advertising, or labeling,
- permanently discontinuing sales, incentives, or supplies to the party violating the regulations,
- temporarily suspending sales, incentives, or supplies to the party violating the regulations, or
- establishing contractual provisions that require compliance with applicable regulatory requirements.

Some commonly asked questions and answers relating to this section include the following:

Am I responsible as a manufacturer if I know that the retailer is selling opened packages?

Yes. If you are a manufacturer and you supply cigarettes to a retailer whom you know opens cigarette packages and sells individual cigarettes, you may be subject to regulatory action for assisting in that violation if you continue to supply cigarettes to that retailer. This is a violation under §1140.16(b).

Is a retailer in violation of the regulations if it distributes free samples of smokeless tobacco at the request of a manufacturer or distributor?

Yes. If you are a retailer and you do not meet the definition of a "qualified adult-only facility," you may be subject to regulatory action for violating the prohibition on the distribution of free samples of smokeless tobacco in anything other than a qualified adult-only facility, even though the manufacturer or distributor asked you to distribute those samples. This is a violation of §1140.16(d)(1).

2. §1140.12--Additional Responsibilities of Manufacturers

The regulation at §1140.12 imposes an additional responsibility on manufacturers. Under this provision, a manufacturer must remove, from each retail location, all:

- self-service displays (also known as "merchandisers"),
- advertising,
- labeling, and
- other items

that the manufacturer owns and that do not comply with the requirements in 21 C.F.R. Part 1140.

With respect to self-service displays, this means that a manufacturer must remove any self-service display that it owns from each retail location unless the self-service display is located in an establishment where no person under age 18 is present or permitted to enter at any time. See § 1140.16 below for a more detailed discussion of this exception.

Some commonly asked questions and answers relating to this section include the following:

What is the manufacturer's responsibility concerning point of sale displays, advertising and labeling?

Under § 1140.12, manufacturers must 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 regulations.

What can the manufacturer, who owns a self-service display at a retail facility, do to comply with the removal requirement?

The manufacturer's options may include:

(1) it can physically remove the non-compliant display from the premises, or
(2) it can alter the display so that it does not violate the regulations. For example, the manufacturer could alter the display so that a person can not buy a product without a retailer's help. However, an electric lock or remote-operated trigger for the display is not acceptable, because the display would then violate the provision requiring retailers to sell cigarettes and smokeless tobacco products only in a direct, face-to-face exchange with the customer. (§1140.16(c))

(3) it can move the display (with the retailer's permission) to a part of the store where customers cannot reach the product themselves.

What must a manufacturer who has advertising and labeling at a retail facility do to comply with the removal requirement?

This provision means that the manufacturer must remove any advertising, labeling, or other items that fail to comply with the requirements in Subpart D, "Labeling and Advertising."**(13)**

For example:

- the manufacturer cannot sell or distribute non-tobacco items (e.g., tee-shirts and hats) or services whic bear the brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other mark of product identification that is similar or identical to that used for any brand of cigarettes or smokeless tobacco (§1140.34(a)), and
- the manufacturer cannot offer any gifts or items in exchange for the purchase of its cigarettes or smokeless tobacco (§1140.34(b)).

Who determines whether a manufacturer – owned item is not in compliance with the regulations?

The initial determination as to whether a manufacturer-owned item complies with the regulations should be made by the manufacturer itself. In most cases, this determination should be very easy to make. A manufacturer is responsible for the removal of all violative self-service displays, advertising, labeling, and other items that it owns from each point of sale.

In other cases, it may not be as easy to determine who is responsible for the self-service display, advertising, or labeling or other item. For example, the manufacturer and retailer may disagree as to who owns the self-service display. However, the regulations require retailers to ensure that all self-service displays, advertising, labeling and other items in their establishments that do not comply with the regulations are removed or brought into compliance with these regulations.

Does a manufacturer have to remove items that other manufacturers own?

Under §1140.12, a manufacturer is responsible for the items that it owns, not items owned by other manufacturers. If you work for a manufacturer and notice an item owned by another company that, in your judgment, violates the regulations, you are under no regulatory obligation to remove the violative item belonging to the other manufacturer. In this situation, you may contact FDA about the potential violation. If FDA determines that the item violates the regulations, it will take appropriate action with respect to the manufacturer that owns the item.

What if I, as the manufacturer, fail to remove a violative item that I own?

If you fail to remove a violative item that you own, FDA may find your product to be misbranded. The FFDCA specifically prohibits misbranding as well as the introduction of a misbranded product into interstate commerce. This means that FDA may take enforcement action against you, including:

- issuing warning letter(s),
- seeking civil money penalties,
- seizing your product,
- seeking an injunction against you,
- criminal prosecution, and/or
- issuing a no-tobacco-sales order on you.

3. §1140.14--Additional Responsibilities of Retailers

If you are a retailer, § 1140.14 specifies additional obligations that you have to ensure that the cigarettes and smokeless tobacco that you or your employees sell are not sold to persons under age 18.

Your obligations, as a retailer, are to:

- not sell cigarettes or smokeless tobacco to anyone younger than 18 years of age;
- verify that any person buying cigarettes or smokeless tobacco is at least 18 years old or older by means of photographic identification (photo ID) containing the bearer's date of birth;
- check identification for all individuals who are under the age of 27;
- sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange between you and your customer, without the help of any electronic or mechanical device.**(14)** In other words, you should see the customer with your own eyes and physically give the product to him or her. Exception: The face-to-face exchange requirement does not apply if the retailer is using a vending machine or self-service

display in a facility where no one younger than 18 years of age is present or permitted to enter at any time. *See* discussion regarding 21 C.F.R. § 1140.16 below for a more detailed discussion of this exception.

- not break open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or any number less than 20 or any quantity of smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use
- remove any violative items, such as self-service displays, advertising**(15)**, and labeling**(16)** that are in the retail establishment.

Some commonly asked questions and answers concerning age verification and relating to this section include the following:

What is the legal age for purchasing cigarettes or smokeless tobacco?

The regulations prohibit the sale of cigarettes and smokeless tobacco to anyone younger than 18 years of age However, the Tobacco Control Act does not affect state or local laws relating to access to tobacco products that are in addition to, or more stringent than, the access provisions in the Tobacco Control Act. Therefore, a state could establish 19 years of age or older as the minimum age for purchasing tobacco products in that state. Some states and localities do, in fact, have more stringent age requirements.

Does the retailer have to be 18 years old to sell the products?

The FDA regulations do not address the age of the sales clerk. However, some state or local laws may set a minimum age for clerks selling tobacco products. We suggest you contact the appropriate authorities in your state to determine if there is such an age requirement for sales clerks.

Can a retailer sell to a child whose parents (or other adults) have sent him/her into a store to purchase these products for the adult's use?

No. The regulations prohibit retailers from selling to anyone younger than 18 years of age.

Can a retailer sell to a child who has a note from a parent or other adult?

No. The regulations prohibit retailers from selling cigarettes or smokeless tobacco to anyone younger than 18 years of age.

Are persons younger than 18 years of age who attempt to buy these products subject to action for violating this law?

FDA's regulations apply only to persons who manufacture, sell, distribute, and advertise these products. However, some states and localities impose penalties on underage children for purchasing, possessing, or using tobacco products.

Can a retailer accept an out-of-state driver's license if it has the customer's picture and date of birth?

Yes, this would be a photo ID containing the bearer's date of birth.

Is the retailer responsible for preventing parents and other adults from purchasing these products for minors?

No. The regulations require only that the retailer verify the age of the purchaser.

Why did FDA decide that retailers must require all customers who are not over the age of 26 to present a photo ID?

Research has shown that it is very difficult for retailers to accurately determine the age of a customer and tha older youth (those who are 16 or 17 years old) are more successful in purchasing tobacco products in retail establishments than are younger youth. Therefore, in order to ensure that older-looking teenagers are asked for identification, FDA concluded that it is important for retailers to request and examine photo IDs from anyone who is under the age of 27.

This recommendation was reiterated in a report issued by a Working Group of State Attorneys General**(17)**, who studied the problem of illegal tobacco sales to minors and concluded that, in order to prevent illegal sales of tobacco products to youth, photo IDs must be requested for persons who are significantly older than the minimum legal age to purchase these products. To address this issue, retailer training programs developed by states, retailer groups, and the tobacco industry typically train retailers to request a photo ID from any customer seeking to purchase tobacco who appears to be under the age of 27**(18)**.

How do I check proof of age?

The regulations require retailers to verify a customer's age by checking a photo ID that shows the person's date of birth. The regulations do not specify the type of photo ID that is acceptable for verifying a person's age, but the most reliable forms of identification are issued by national governments, if they contain the bearer's date of birth and a photograph (such as federal employee or military identification cards, passports), state governments (such as driver's licenses), and local governments (such as employee identification cards that contain the bearer's date of birth and a photograph). Some private companies also publish guides containing photographs and descriptions of valid licenses; these guides may be helpful in distinguishing valid or genuine identification cards from fraudulent ones.

The regulations specify that you should check proof of age for anyone under the age of 27, but determining someone's age by looking at his or her physical appearance alone can be difficult. Some people look younger than they really are, while others look older than they are. You should use your best judgment in order to protect yourself and your customers – particularly your underage customers. For example, if you are not sure whether someone is older than 18 years of age, and you cannot tell whether he or she is 27 years old, you should ask for a photo ID anyway; this will let you determine whether he or she is legally entitled to purchase cigarettes and smokeless tobacco and take the guesswork out of the transaction.

Although the regulations do not specify at what point you should verify a consumer's age, FDA suggests that you ask your customers for photo IDs before you give them cigarettes or smokeless tobacco. This will enable you to hold onto the product if, after seeing the customer's identification, you discover that the person is too young to purchase the product or you think that the identification card is a fake.

What should a salesclerk do when they suspect a customer's ID is fake or has been changed?

If a retailer suspects that an ID is unreliable, the retailer should refuse the sale. Selling to an underage customer violates the regulations. Fake ID cards may be difficult to detect, but many fake cards are obvious due to their poor quality. There are also some companies that sell manuals showing pictures of current, valid driver's licenses for each state. These manuals may help the retailer to determine whether or not an ID card i valid.

If a wholesale operation delivers to a store or gas station, and the only employee present at the time of delivery is someone younger than 18 years of age, can the delivery be made?

Yes. In that situation, the wholesaler is selling to a retailer, not a customer. However, state or local laws may prohibit the delivery of tobacco products to persons younger than a certain age. We suggest you contact the appropriate authorities in your state to determine if there is such an age requirement for sales clerks.

How do the regulations affect retailers who sell only tobacco products?

The regulations apply equally to retailers that sell only tobacco products and those that sell tobacco products in addition to other things.

Can I sell single cigarettes?

No, under § 1140.14(d), you may not sell individual cigarettes (often called "singles" or "loosies") or small quantities of smokeless tobacco. FDA reviewed several reports indicating that stores in various parts of the United States were willing to sell single cigarettes to children. Single cigarettes or small quantities of smokeless tobacco are generally cheaper than a full sized pack of cigarettes or a full size smokeless tobacco package and, as a result, may entice children and adolescents to try using these products. Part 1140.14 does not apply to shipping cartons as discussed below.

As described below, there is a very limited exception to this requirement, and it applies only to packaged, single cigarettes that are sold in vending machines that are located in places where no person younger than 18 years of age is present or permitted to enter at any time.

Can I break apart shipping cartons?

Yes, you can open a shipping container in order to sell individual cartons or packages and, in the case of cigarette cartons, open cigarette cartons to sell individual packages. However, under §1140.14, you cannot:

- break open a cigarette package or carton to sell individual cigarettes or any number less than 20 cigarettes; or
- break open a package of cigarette tobacco or smokeless tobacco to sell a portion of that product that is smaller than the smallest package distributed by the manufacturer for individual consumer use.

What is the retailer's responsibility concerning point of sale displays, advertising and labeling?

Under § 1140.14(e), each retailer must ensure that all self-service displays, advertising, labeling, and other items located in its establishment that do not comply with the regulations are removed or are brought into compliance.

It should be noted also that the regulations also require manufacturers to remove items that they own if those items violate the regulations.

Am I responsible for the actions of my employees?

Yes. Employers are responsible for their employees' actions**(19)**. This is true even if the employer does not know about the employee's actions or where the employee failed to take corrective action as requested by his or her employer. As an employer, you are generally responsible for the actions of your business, whether it is in the manufacturing, distributing or retail sector. This includes being responsible for the acts of people who work for you.

For this reason, even though the regulations do not require you to train or educate your employees about their responsibilities, FDA recommends that you develop educational or training materials to require your employees to check proof of age, to know that the regulations prohibits sales to anyone younger than 18 years of age, to teach them how to check proof of age of anyone under 27, and to inform them of the other requirements in the regulations. If your state or local government has additional requirements, you may add them to your training program as well. In addition, if you are found to be in violation of the regulations, your civil money penalties may be reduced if you have an approved training program for your employees.

4. §1140.16--Conditions of Manufacture, Sale, and Distribution

§1140.16 creates several different regulatory requirements. Some apply only to manufacturers, such as the restriction on product names and some apply only to retailers, such as the restriction on "impersonal" modes of sale, while others apply to manufacturers, distributors, and retailers, such as the requirement establishing minimum package size for cigarettes.

§1140.16(a)—Restriction on product names

Under §1140.16(a), manufacturers may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product unless the 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.

FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate to address those concerns. As announced in the guidance document published on May 7, 2010, while FDA has this issue under consideration, it intends to exercise its enforcement discretion concerning 21 C.F.R. 1140.16(a) not to commence enforcement actions under this provision for the duration of its consideration where:

(1) The trade or brand name of the cigarettes or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or

(2) The first marketing or registration in the United States of the tobacco product occurs before the first marketing or registration in the United States of the non-tobacco product bearing the same name; provided, however, that the tobacco and non-tobacco product are not owned, manufactured, or distributed by the same related, or affiliated entities (including as a licensee)**(20)**.

§1140.16(b)--Minimum cigarette package size

If you are a cigarette manufacturer, distributor, or retailer, the regulations state that the minimum cigarette package size must contain 20 cigarettes. Most cigarette packs sold in the U.S. contain 20 cigarettes. If you make, distribute or sell cigarette packs that contain less than 20 cigarettes you will be in violation of these regulations and subject to regulatory action.

This provision exists because studies and reports indicate that small cigarette packs, which can contain anywhere from 8 to 18 cigarettes and are commonly called "kiddie packs," are very popular with children and adolescents, partly because they are easier to conceal, and are less expensive than full-size packs. (Young people, who generally have little disposable income, can be particularly sensitive to the price of cigarettes and may choose not to smoke as the price increases.)**(21)** As a result, FDA imposed a minimum cigarette packag size of 20 cigarettes to keep "kiddie packs" out of the hands of persons younger than 18 years of age.

Some commonly asked questions relating to this section include the following:

Do I have to inspect each package to make sure it contains 20 cigarettes?

If you're a distributor or retailer, FDA does not expect you to open each cigarette pack to check whether it contains 20 cigarettes. You can rely on the manufacturer's claim or labeling that the pack contains 20 cigarettes.

If you're a manufacturer and your cigarette packs fail to contain at least 20 cigarettes in each pack, FDA may find your packages to be misbranded and take regulatory action against you.

Is there a minimum package size for smokeless tobacco?

The regulations do not contain a minimum package size for smokeless tobacco. This is due, in part, to the fac that smokeless tobacco comes in several forms, e.g., moist snuff, twist, plug, so creating a minimum package size for all forms of smokeless tobacco is not feasible. However, retailers may not sell any quantity of smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use. 21 C.F.R. § 1140.14(d). For example, retailers may not open the original manufacturer's package of smokeless tobacco and sell a portion of it to consumers in smaller cups, bags, or other containers.

Is there any exception to the minimum package size?

There is a very limited exception, and it applies only to packaged, single cigarettes sold in vending machines that are located in places where no one younger than 18 years of age is present or permitted to enter at any time.

§1140.16(c)--Vending machines, self-service displays, mail order sales and other "impersonal" modes of sale

If you are a retailer, the regulations require you to sell cigarettes or smokeless tobacco to your customers in a direct, face-to-face exchange, with limited exceptions. This section reinforces this requirement by prohibiting retailers from engaging in "impersonal" modes of sale. There are, however, two important exceptions. These exceptions are:

- M**ail order sales are permitted, except that mail-order redemption of coupons and distribution of free samples through the mail are not permitted(22).**
- **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.**

Under this exception, a retailer may have a vending machine or self-service display **only if**:
- NO ONE younger than 18 years of age is present at the facility at any time, and
- NO ONE younger than 18 years of age is permitted in the facility at any time.

The purpose of this exception is to allow retailers to use vending machines and self-service displays if their retail facility, whether it's a bar, a private club, or a factory, is off limits to anyone younger than 18 years of age at all times.

Some commonly asked questions about the exception include the following:

What does FDA mean by a "direct, face-to-face exchange?"

Retailers are required to physically hand the product to the consumer. This means that, if you are a retailer, you and your employees must:

- See the customer directly, without the use of electronic aids (such as a television screen) or mechanical devices (such as an intercom), and, if necessary, verify that he or she is at least 18 years old;
- obtain the product for the customer, and
- hand the product to the customer.

This requirement also helps retailers to verify the customer's age and to prevent children from shoplifting these products. Shoplifting is another means of getting cigarettes and smokeless tobacco products into the hands of children.

Am I permitted to use vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays in my retail establishment?

Vending machines and self-service displays are only allowed in facilities where only people 18 years of age or older are present, or permitted to enter. 21 C.F.R. 1140.16(c)(2)(ii). The regulations do not specify how you should prevent people younger than 18 years of age from entering your facility if you are a facility where vending machines or self-service displays for tobacco products are located. It is up to the retailer to determin how best to comply with the requirements based on their individual retail establishment. One approach might be to use an employee to check for proof of age at the door. If the customer is older than 18 years of age, he or she can enter the facility; however, if the customer is younger than 18 years of age, he or she is barred

from entering the premises. But, regardless of the approach you use, if you want to qualify for the exception, it is important that no one younger than 18 years of age is present or permitted in the facility at any time.

What types of retail establishments may qualify to use vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays within the meaning of 21 C.F.R. 1140.16(c)(2)(ii)?

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?

A self-service display is any item that permits a consumer to remove a cigarette or smokeless tobacco produc 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 ove 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

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 actior 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;
(3) is not located next to or immediately across from (in any direction) a space that is used primarily for yout -oriented marketing, promotional, or other activities;
(4) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpos of distributing free samples of smokeless tobacco adhering to this subparagraph; and
(5) is enclosed by a barrier that:

a. is constructed of, or covered with, an opaque material (except for entrances and exits);
b. extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrie 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);
c. 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
d. does not display on its exterior—

- any tobacco product advertising;
- a brand name other than in conjunction with words for an area or enclosure to identify an adult only facility; or
- any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate § 1140.34(c).

In addition, the free samples of smokeless tobacco that are permitted to be taken out of the qualified adult-only facility are limited to one package that contains no more than 0.53 ounces (15 grams) of smokeless tobacco per adult consumer per day.

Some commonly asked questions and answers relating to this section include the following:

Can a manufacturer, distributor or retailer distribute free samples of smokeless tobacco?

Yes, a manufacturer, distributor or retailer may distribute free samples of smokeless tobacco, but only in a qualified adult-only facility.

What are the advertising restrictions for "qualified adult-only facilities that distribute free samples of smokeless tobacco?"

Under § 1140.16(d)(2)(iii)(F), qualified adult-only facilities are not permitted to display on the exterior of the facility tobacco product advertisements, a tobacco product brand name except for purposes of identifying an area or enclosure as an adult-only facility; or words that imply that the manufacturer, distributor, or retailer has a sponsorship that violates § 1140.34(c).

§1140.16(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 that do not comply with Subpart D of 21 C.F.R. Part 1140 and other applicable requirements.

As a manufacturer, distributor, or retailer, you may not sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco products that have labels, labeling or advertising that do not comply with

these regulations. Products that do not comply with these regulations are considered to be misbranded under the FFDCA, and if you try to sell or further distribute these products, you will be misbranding the product too, and that may lead to regulatory action against you. Also, if you change the manufacturer's package, label, labeling or advertising in a way that renders the product misbranded under the FFDCA, this may lead to regulatory action against you if you try to sell or distribute these products.

If you think that a product's label, labeling or advertising does not comply with the regulations, FDA recommends that you not sell or distribute the product, return it to the responsible party, and ask for product that comply with the regulations.

C. Subpart D--Labeling and Advertising

Subpart D, "Labeling and Advertising" contains 3 sections: (1) §1140.30 – "Scope of permissible forms of labeling and advertising;" (2) §1140.32 – "Format and content requirements for labeling and advertising;" an (3) §1140.34 – "Sale and distribution of nontobacco items and services, gifts and sponsorship of events."

1. §1140.30--Scope of Permissible Forms of Labeling and Advertising

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.

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.

§1140.30(a)(1) describes the forms of labeling and advertising that are covered under the regulations. A manufacturer, distributor, or retailer can distribute labeling and advertising that bears a cigarette or smokeless tobacco brand name (or any other indicia of tobacco product identification) in or on:

- Newspapers;
- Magazines;
- periodicals or other publications, whether periodic or of limited distribution;
- billboards, posters, and placards;
- non-point-of-sale promotional material, including direct mail;
- point-of-sale promotional material;
- audio or video formats delivered at point-of-sale; and

"Point-of-sale" is any location at which a consumer can purchase cigarettes or smokeless tobacco for his or her own consumption. In other words, point-of sale does not have to be fixed in one location or the same location (although most points-of-sale will probably be fixed structures such as stores). If you sell cigarettes from a truck, any advertising and marketing materials that appear on the truck, or at the location where consumers purchase the product, or that are given to consumers at the time of purchase, would be point-of-sale materials.

§ 1140.30(a)(2) permits a manufacturer, distributor, or retailer to disseminate or cause to be disseminated advertising and labeling for cigarettes and smokeless tobacco products that are not in any of the media listed in § 1140.30(a)(1) as long as the FDA is given notice 30 days prior to the use of the medium and the party discusses in the notice the extent to which the advertising and labeling may be seen by those younger than 1 years of age.

Some commonly asked questions and answers relating to this section include the following:

What to do if you want to use a new form of advertising or labeling that is not listed in § 1140.30

§ 1140.30 applies regardless of whether you are a manufacturer, distributor or retailer. In developing this section, FDA listed several types of tobacco advertising and labeling. If you want to distribute advertising or labeling in a medium that is not listed in section 1140.30(a)(1), you must notify FDA 30 days before

distributing that advertising or labeling in that medium. The regulations require you to describe the medium that you intend to use and to discuss the extent to which the advertising or labeling may be seen by people younger than 18 years of age. The notice should be sent to the Office of Regulations (Compliance) at the address listed under Agency Contacts below.

2. §1140.32--Format and Content Requirements for Labeling and Advertising

*As noted in the Discussion section, FDA announced on May 7, 2010 that it is exercising enforcement discretio concerning 21 C.F.R. 1140.32(a) and therefore, regulatory requirements under that section have not been discussed in this guidance document.**(23)***

3. §1140.34--Sale and Distribution of Non-Tobacco Items and Services, Gifts, and Sponsorship of Events

§ 1140.34 establishes restrictions on three forms of promotions: (1) non-tobacco items (such as hats and tee shirts) or services which bear the tobacco brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or any indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco; (2) gifts or items in consideration of purchasing cigarettes or smokeless tobacco or in consideration of furnishing evidence (such as credits, proofs-of-purchase, or coupons) of a purchase of cigarettes or smokeless tobacco; and (3) sponsorship of any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name, 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.

§1140.34(a)--Non-tobacco items and services

The regulations establish restrictions on promotional items and services. This provision applies to manufacturers and to distributors of imported products. If you're a manufacturer or distributor of imported cigarettes or smokeless tobacco, you cannot:

- *Market,*
- *License,*
- *Distribute,*
- *Sell, or*
- *Cause to be marketed, licensed, distributed or sold*
  any non-tobacco item or service that 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 that is the same or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Some commonly asked questions and answers relating to this section include the following:

Can a manufacturer or distributor of tobacco products sell nontobacco products (e.g., tee-shirts, hats, mugs, bags) that have a cigarette or smokeless tobacco product 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 the product identification identical or similar to that used for any brand of cigarettes or smokeless tobacco?

No. A manufacturer or distributor of tobacco products may not market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold, nontobacco products (e.g., tee-shirts, hats, mugs, bags) that bear a cigarette or smokeless tobacco product 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 the product identification identical or similar to that used for any brand of cigarettes or smokeless tobacco. This means that, as a manufacturer or distributor, not only can you not sell, distribute, market, or license these products, but you also cannot cause another person to sell, distribute, market or license these products.

§1140.34(b)--Gifts

§ 1140.34(b) prohibits manufacturers, distributors and retailers from offering, or causing to be offered, any gift or item (other than cigarettes or smokeless tobacco) in consideration of purchasing cigarettes or smokeless tobacco or in consideration of furnishing evidence of a purchase of cigarettes or smokeless tobacco such as proofs-of purchase, coupons, credits, or other evidence of such a purchase. The restriction also applies regardless of whether the consumer can redeem his or her proofs-of-purchase for all or part of the gift's or item's value.

Some commonly asked questions and answers relating to this section include the following:

Can coupons be credited toward a gift or item?

No, the regulations prohibit the offering of a gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of furnishing evidence of such a purchase

Can a manufacturer, distributor or retailer have a catalog that offers merchandise in exchange for points or certificates that you earn by purchasing cigarettes or smokeless tobacco?

No, a manufacturer, distributor, or retailer cannot have a catalog that offers merchandise in exchange for points or certificates that you earn by purchasing cigarettes or smokeless tobacco.

Can a manufacturer, distributor, or retailer, offer to give an item away for free in exchange for a certain number of proofs-of-purchase or offe the item at a low cost in exchange for a certain number of proof-of-purchase.

No, a manufacturer, distributor, or retailer, cannot offer to give an item away for free or offer an item at a lov cost in exchange for any number of proofs-of-purchase.

§1140.34(c)--Sponsorship

In brief, if you are a manufacturer, distributor, or retailer, you cannot sponsor or cause to be sponsored any:

- athletic event,
- musical event,
- artistic event,
- social or cultural event,
- entry in any event, or
- team in any event
  if that sponsored event, entry or team would be 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 the product identification identical or similar to, or identifiable with, those used for any brand c cigarettes or smokeless tobacco.

For example, for the "BRANDNAME Cigarettes" brand, assume that the package design for BRANDNAME Cigarettes features an orange and white diamond. Under § 1140.34(c), the manufacturer cannot sponsor a basketball tournament if it would call the tournament the "BRANDNAME Cigarette Tournament" or sponsor the tournament in the name "BRANDNAME Cigarettes." It also cannot sponsor a team using the "BRANDNAME Cigarettes" name or even sponsor a team using only the brand's orange and white diamond.

The regulations do permit manufacturers, distributors, and retailers to sponsor events, teams and entries using their corporate names, so long as the corporate name was registered and in use in the United States before January 1, 1995 and the corporate name itself does not use the brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of the product identification identical or similar to, or identifiable with, those used for any cigarette or smokeless tobacco brand. For example, if the XXX Company makes BRANDNAME Cigarettes, the company can sponsor the "XXX Company Tournament" if the name "XXX Company" and the company itself was registered and in use before January 1, 1995. However, a BRANDNAME Tobacco Company that makes BRANDNAME Cigarettes cannot sponsor the "BRANDNAME Tournament" because the company name and brand name are similar if not identical.

Some commonly asked questions and answers relating to this section include the following:

Can a brand name of a cigarette or smokeless tobacco product be used in the sponsorship of a sporting event?

No. Sponsorship of athletic, musical, artistic, or other social or cultural events in the brand-name, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicia of product identification o cigarettes or smokeless tobacco is prohibited.

Effective Date for the Regulations

These regulations were published on March 19, 2010, and are effective on June 22, 2010. This enables manufacturers, distributors and retailers to take whatever steps they need to settle their existing business affairs, to adjust their current business operations and to plan future business operations that comply with these regulatory requirements.

If you violate any of these regulations, FDA may initiate enforcement action against you. However, as discussed above, FDA intends to exercise enforcement discretion with respect to two provisions of the regulations: 21 CFR sections 1140.16(a) and 1140.32(a) of the final rule.
Section 1140.16(a).

Under this section of the final regulations, manufacturers may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product unless the trade or brand name was on both the tobacco product and a nontobacco product sold in the United States on January 1, 1995. FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate to address those concerns. While FDA has this issue under consideration, it intends to exercise its enforcement discretion concerning 21 C.F.R. 1140.16(a) not to commence enforcement actions under this provision for the duration of its consideration where:

(1) The trade or brand name of the cigarette or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or

(2) The first marketing or registration in the United States of the tobacco product occurs before the first marketing or registration in the United States of the non-tobacco product bearing the same name; provided, however, that the tobacco and non-tobacco product are not owned, manufactured, or distributed by the same related, or affiliated entities (including as a licensee)**(24)**.

Section 1140.32(a).

Under this section of the final rule, manufacturers, distributors, and retailers must use only black text on a white background for cigarette labeling or advertising (with certain exceptions). The United States District Court for the Western District of Kentucky recently issued an order permanently enjoining FDA from enforcing section 21 CFR 1140.32(a) (formerly section 897.32(a) of the 1996 final rule) (Commonwealth Brands, Inc. v United States, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010)). The injunction prevents enforcement of this provision against the parties to the case in any jurisdiction in the United States. On March 8, 2010, the government filed an appeal from that order.

In light of the court's order in Commonwealth Brands, FDA intends to exercise its enforcement discretion concerning 21 CFR 1140.32(a) not to commence enforcement actions under this provision during the pendency of the litigation irrespective of whether the entity is a party to the pending lawsuit or located in the Western District of Kentucky**(25)**.

How to report violations to FDA?

Members of the general public can report violations to FDA's Center for Tobacco Products through our website (http://www.fda.gov/TobaccoProducts/default.htm[5]), by e-mail (AskCTP@fda.hhs.gov), or by phone (1-877-CTP-1373).

Agency Contacts

Registration and Listing Branch
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20857
1-877-287-1373

Office of Regulations (Compliance)
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20857
1-877-287-1373

Division of Small Business Assistance
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20857
1-877-287-1373

Who is Subject to the Regulations?	Regulations	Where I Can Find This Information in this Guidance Document

Manufacturers, Distributors**(26)**, and Retailers	1140.10 – General Responsibilities	See page 10 in PDF
Manufacturers	1140.12 – Additional Responsibilities of Manufacturers	See page 10 in PDF
Retailers	1140. 14 – Additional Responsibilities of Retailers	See page 13 in PDF
Manufacturers, Distributors, and Retailers	1140.16 – Conditions of Manufacture, Sale and Distribution	See page 18 in PDF
Manufacturers, Distributors, and Retailers	1140.30 – Permissible Labeling and Advertising	See page 24 in PDF
Manufacturers, Distributors, and Retailers	1140.32 – Format and Content Requirements, Labeling and Advertising	See page 26 in PDF
Manufacturers, Distributors, and Retailers	1140.34 – Sale and Distribution of Nontobacco Items and Services, Gifts, and Sponsorship of events	See page 26 PDF

Appendix A--21 CFR Part 1140

An electronic version of 21 CFR Part 1140 is available on the Internet at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=4bfa1e83ce026f1d194a73e021ecfe99;rgn=div2;view=text;node=20100319%3A1.5;idno=21;cc=ecfr;start=1;size=25

Footnotes

1) This guidance has been prepared by the Center for Tobacco Products at the U.S Food and Drug Administration.
2) 75 FR 13225 (March 19, 2010).
3) 61 FR 44396 (Aug. 28, 1996).
4) Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, The Health Consequences o Smoking: a Report of the Surgeon General, 2004.
5) Congressional Record, S6407, June 10, 2009, Statement of Senator Kennedy.
6) 75 FR 13225 (March 19, 2010).
7) 75 FR 25272 (May 7, 2010).
8) See Guidance to Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2), FDA/CTP, (Dec. 23, 2009), at Question 6, http://www.fda.gov/downloads/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/UCM195420.pd
9) Id. at Question 5.
10) 21 C.F.R. 1140.3(d).
11) 21 C.F.R. 1140.3(c).
12) 21 C.F.R. 1140.3(h).
13) As noted in the Discussion section, FDA is exercising enforcement discretion concerning 21 C.F.R. 1140.3 (a) and therefore, these regulatory requirements have not been included in this guidance document.
14) For example, vending machines that dispense cigarettes or smokeless tobacco products with the purchase of a token or that can be disabled by remote control do not meet the requirement for a direct, face-to-face exchange. These measures do not sufficiently guard against children's access to tobacco products. 61 FR 44451, comment 69.
15) See Discussion section regarding enforcement discretion.
16) Id.
17) Working Group of State Attorneys General. No Sale: Youth, Tobacco and Responsible Retailing.

Developing Responsible Retail Sales Practices and Legislation to Reduce Illegal Tobacco Sales to Minors. Findings and Recommendations. Baltimore, MD: State of Maryland, Office of the Attorney General, 1994.
18) Id.
19) See, e.g., U.S. v. Dotterweich, 320 U.S. 277 (1943) (holding that a corporate official is strictly criminally liable for his company's violations of the FFDCA, even in the absence of wrongful action on his part); U.S. v. Park, 421 U.S. 658 (1975) (reiterating holding of Dotterweich). See also, Pettit v. Retrieval Master Creditors Bureau, Inc., 211 F.3d 1057 (7th Cir. 2000) (debt collection company is responsible for its employees' violations of the Fair Debt Collection Practices Act); U.S. EEOC v. AIC Sec. Investigations, 55 F.3d 1276 (1995) (employer is liable for employees' violations of law).
20) 75 FR 25282 (May 7, 2010).
21) Lewit, E.M., D. Coate, and M. Grossman, "The Effects of Government Regulation on Teenage Smoking," Journal of Law and Economics, vol. XXIV, No. 3, pp. 545–569, 1981.
22) The regulations permit mail-order sales of cigarettes and smokeless tobacco. 21 C.F.R. 1140.16(c)(2)(ii). The Prevent All Cigarette Trafficking Act (PACT Act) (P.L. 111-154) was enacted on March 30, 2010, to amend the Jenkins Act to revise provisions governing the collection of taxes on, and trafficking in, cigarettes and smokeless tobacco. Among other requirements, the PACT Act requires the U.S. Postal Service (USPS) to refuse to accept for delivery or transmit through the mails any package that it knows or has reasonable cause to believe contains any cigarettes or smokeless tobacco.23)
23) 75 FR 25271 (May 7, 2010).
24) 75 FR 25271 (May 7, 2010).
25) 75 FR 25271 (May 7, 2010).
26) A distributor includes any person who imports cigarettes or smokeless tobacco. 21 C.F.R. 1140.3(c).

Links on this page:

1. http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM21442 4.pdf
2. http://www.regulations.gov/
3. http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm
4. http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm
5. http://www.fda.gov/TobaccoProducts/default.htm