Guidance for Industry

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

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with the docket number FDA-2010-D-0277.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877- CTP-1373 (1-877-287-1373) Monday-Friday, 9:00 a.m. – 4:00 p.m. EDT.

Additional copies are available online at https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Building 71, Room G33, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

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See additional PRA statement in section X of this guidance.

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Guidance for Industry[1]

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

This 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 implementing 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 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:

- what and who are subject to the regulations;
- prohibition on the sale and distribution of certain tobacco products to persons younger than 18 years of age;
- restrictions on access, which consist largely of requirements concerning the sale of cigarettes and smokeless tobacco; and
- labeling and advertising restrictions

The regulations currently apply to cigarettes, including roll-your-own tobacco;[3] cigarette tobacco;[4] and smokeless tobacco products (e.g., moist snuff, snus, dry snuff, nasal snuff, loose leaf chewing tobacco, plug chewing tobacco, and twist chewing tobacco).

FDA's guidances, including this 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

[1] This guidance document has been prepared by the Center for Tobacco Products at the Food and Drug Administration.

[3] The definition of "cigarette" includes roll-your-own tobacco. See Section 900(3) of the FD&C Act; 21 C.F.R. 1140.3(a).

[4] Unless otherwise stated, requirements that apply to cigarettes also apply to cigarette tobacco. See section 900(4) of the FD&C Act; § 1140.3(b).

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), enacted on June 22, 2009, amends the Food, Drug, and Cosmetic Act (FD&C Act) and provides FDA with the authority to regulate tobacco products. Section 102 of the Tobacco Control Act requires FDA to publish final regulations regarding cigarettes and smokeless tobacco which are identical in their provisions to the regulations promulgated by FDA in 1996 (Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (1996 final regulations),[5] 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. Cigarette smoking causes approximately 440,000 deaths each year.[6] Moreover, advertising, marketing, and promotion of tobacco products have been "especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth" (section 2(15) of the Tobacco Control Act). The use of tobacco products is a "pediatric disease," and an effective program to address this disease includes restrictions on youth access and restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people. See sections 2(1), (26), (30)-(32) of the Tobacco Control Act.

Congress recognized that 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. [7]

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 (CFR), Part 1140.[8] 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 labeling, marketing, and advertising of cigarettes and smokeless tobacco. Among other requirements, 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;

[5] See 61 FR 44396 (Aug. 28, 1996).
[6] See 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 of Smoking: a Report of the Surgeon General*, 2004.
[7] See Congressional Record, S6407, June 10, 2009, Statement of Senator Kennedy.
[8] See 75 FR 13225 (March 19, 2010).

- prohibit the sale of cigarettes and smokeless tobacco products through vending machines and self-service displays, except in facilities where individuals under the age of 18 are not present, or permitted to enter at any time;
- 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 the regulations establishes format and content requirements for labeling and advertising to allow only black text on a white background, with limited exceptions. Section 1140.34(b) states that no manufacturer, distributor, or retailer may offer, or cause to be offered, any gift or item (other than cigarettes or smokeless tobacco) in consideration of purchasing cigarettes or smokeless tobacco. On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found §§ 1140.32(a) and 1140.34(b) to be unconstitutional under the First Amendment. (See *Discount Tobacco et al v. United States*, 674 F.3d 509 (6th Cir. 2012) (*cert. denied*)). Therefore, FDA will not seek to enforce these provisions.

III. DISCUSSION

A. What and Who Are Subject to the Regulations?

The Tobacco Control Act amends the FD&C Act and provides FDA with the authority to regulate tobacco products. FDA has issued part 1140, which prohibits the sale of cigarettes and smokeless tobacco to any person under age 18 and places restrictions on marketing, labeling, and advertising of cigarettes and smokeless tobacco products.

Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) 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). The term does not include an article that is a drug under section 201(g)(1) of the FD&C Act, a device under section 201(h) of the FD&C Act, or a combination product under section 503(g) of the FD&C Act (21 U.S.C. 353(g)). Also, a tobacco product must not be marketed in combination with any other article or product that is regulated under the FD&C Act (section 201(rr)(4) of the FD&C Act).

Part 1140 currently covers the following tobacco products:

- cigarettes, including roll-your-own tobacco,[9]
- cigarette tobacco,[10] and
- smokeless tobacco products (e.g., moist snuff, snus, dry snuff, nasal snuff, loose leaf chewing tobacco, plug chewing tobacco, and twist chewing tobacco).

[9] The definition of "cigarette" includes roll-your-own tobacco. See Section 900(3) of the FD&C Act; 21 C.F.R. 1140.3(a).

[10] Unless otherwise stated, requirements that apply to cigarettes also apply to cigarette tobacco. See section 900(4) of the FD&C Act; § 1140.3(b).

The regulations apply to persons who manufacture, distribute, or sell cigarettes, including roll-your own-tobacco; cigarette tobacco; and/or smokeless tobacco.

Greater detail is provided in the discussion of Definitions, section V.C of this guidance. A summary table is also provided in **Attachment 1 — Regulation References**.

B. Do Other Regulatory Requirements Apply to Me?

The Tobacco Control Act, the FD&C Act as amended by the Tobacco Control Act, other laws amended by the Tobacco Control Act, and other FDA regulations may impose requirements on you in addition to those contained in part 1140. For example, section 904 of the FD&C Act (21 U.S.C. 387d) 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 of the FD&C Act and the Tobacco Control Act. These guidances are posted on our Web site at: https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance. Similarly, the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333 et seq.) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 et seq.) require companies to place warnings on cigarette and smokeless tobacco packages and in advertisements.

If you fail to comply with a statutory or regulatory requirement that applies to you, tobacco products that you manufacture, distribute, advertise, or sell may be considered adulterated or misbranded. You may then be subject to regulatory and enforcement actions, including 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 state or local requirements apply to you, we suggest that you contact your state or local authorities.

IV. SALE AND DISTRIBUTION REQUIREMENTS

The regulations in 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 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 1996 final regulations were removed at the direction of the Supreme Court in 2000.

At the direction of Congress as part of the passage of the Tobacco Control Act, the current regulations at part 1140 were issued, largely identical to the 1996 version with some specifically identified changes. The regulations are not designed or intended to prevent sales to adults or interfere with a manufacturer's, distributor's, or retailer's ability to communicate truthful and nonmisleading information to adult consumers.

The regulations are divided into two main components: (1) access provisions, which consist largely of requirements concerning the sale of cigarettes and smokeless tobacco; and (2) marketing, labeling, and advertising restrictions.

To help you understand these requirements, this guidance examines each section in the order in which it appears in part 1140 and provides answers to several questions relating to each section of these requirements. An electronic version of part 1140 is available on the Internet at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-K/part-1140.

Sections V through VII of this guidance discuss subparts A, B, and D of part 1140, respectively.

V. PART 1140, SUBPART A — GENERAL PROVISIONS

Subpart A on general provisions contains three sections:

- § 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;
- § 1140.2 Purpose, which states the purpose of the regulations; and
- § 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.

A. Section 1140.1 — Scope

Section 1140.1 explains that the regulations establish restrictions, under the FD&C Act, on the sale, distribution, and use of cigarettes and smokeless tobacco. It also explains that the failure to comply with any applicable provision in part 1140 may render the cigarettes or smokeless tobacco product "misbranded" under the FD&C Act. Among other actions related to misbranding, causing a tobacco product to be misbranded after shipment in interstate commerce or introducing a misbranded tobacco product into interstate commerce is prohibited under the FD&C Act (section 301 of the FD&C Act (21 U.S.C. 331)).

B. Section 1140.2 — Purpose

Section 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 each year. Other information available to FDA indicated that most cigarette smokers started before they reached 18, and research suggests that the younger people are when they begin to smoke, the more likely they are to become adult smokers.[11] By reducing the number of children who start smoking, the regulations could lower the death rate attributed to cigarettes (approximately 440,000 Americans annually).

C. Section 1140.3 — Definitions

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

1. What Products Are Subject to Regulation Under Part 1140?

The regulations apply to some, but not all, tobacco products. Specifically, the regulations apply to cigarettes, including roll-your-own tobacco;[12] cigarette tobacco; and smokeless tobacco. These items are defined as:

- The term ***cigarette*** as defined in section 900(3) of the FD&C Act (and § 1140.3(a))
  "(A) 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
  (B) 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 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

[11] See President's Cancer Panel, "Promoting Healthy Lifestyles," p. 64, U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, 2007, available at http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp07rpt/pcp07rpt.pdf.

[12] The definition of "cigarette" includes roll-your-own tobacco. See Section 900(3) of the FD&C Act; 21 C.F.R. 1140.3(a).

likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own-tobacco."[13] Accordingly, a 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.[14] In other words, a product is a "cigarette" despite any other names that may be used to describe it, if its appearance, the kind of tobacco used in its filler, or the packaging and labeling indicates that it is likely to be offered to a consumer or bought by the consumer as a cigarette. In addition, roll-your-own tobacco also meets the definition of cigarette and is thus subject to the restrictions in these regulations.

Currently, other tobacco products, such as cigars, little cigars, and pipe tobacco, are not subject to these regulations.

- The term ***cigarette tobacco*** is defined in section 900(4) of the FD&C Act and in § 1140.3(b) 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 also apply to cigarette tobacco." *Under the FD&C Act and these regulations, cigarette tobacco is treated the same as cigarettes unless specifically stated otherwise.* Thus, cigarette tobacco is subject to the restrictions in these regulations.

- The term ***smokeless tobacco*** is defined in section 900(18) of the FD&C Act and in § 1140.3(i) as "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*" (emphasis added).

  There are many types of smokeless tobacco. The principal names for the various types of smokeless tobacco include: 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 between domestic cigarettes or smokeless tobacco products and products that are imported into the United States. If you import, distribute, or offer imported cigarettes or smokeless tobacco products for sale in the United States, you and your products must comply with these regulations.

2. Who Is Subject to Regulation Under Part 1140?

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

[13] Section 900(3) of the FD&C Act and 21 CFR 1140.3(a). See also guidance to industry and FDA staff entitled *General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors* (Edition 2), FDA/CTP, (Dec. 23, 2009) (guidance on General Q&As on Flavored Tobacco), at Question 6, available at https://www.fda.gov/media/116681/download

[14] See guidance on General Q&As on Flavored Tobacco, at Question 5.

- The term ***manufacturer*** includes any person, "including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product."[15]

  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 did not make the finished cigarettes themselves.

- The term ***distributor*** includes 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).[16]

  Most distributors who are subject to regulation under 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 likely a "common carrier"[17] and are not subject to 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 cigarettes or smokeless tobacco that are imported into the United States. Persons who purchase bulk shipments of cigarettes and/or smokeless tobacco 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 part 1140.

- The term ***retailer*** includes 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 [these regulations]."[18] 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 represent only a fraction of total sales, the store is a "retailer"

[15] § 1140.3(d).
[16] § 1140.3(c).
[17] A "common carrier" means "any person (other than a local messenger service or the United States Postal Service) that holds itself out to the general public as a provider for hire of the transportation by water, land, or air of merchandise (regardless of whether the person actually operates the vessel, vehicle, or aircraft by which the transportation is provided) between a port or place and a port or place in the United States" (15 U.S.C. 375(3)).
[18] § 1140.3(h).

subject to regulation under 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 operate facilities where vending machines or self-service displays (or merchandisers) of cigarettes and/or smokeless tobacco are located, even if they technically do not own the vending machines or self-service displays themselves. The reason why persons who operate facilities where vending machines or self-service displays are located are considered retailers is described in more detail in the discussion for § 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 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 for personal consumption, you are a manufacturer (because you made the cigarettes) and a retailer (because you sold them to individuals).

3. Who Is Not *Subject to Regulation Under Part 1140?*

Chapter IX of the FD&C Act does not apply to growers of tobacco, tobacco warehouses, and tobacco grower cooperatives, unless they are also manufacturers (section 901(c)(2) of the FD&C Act (21 U.S.C. 387a(c)(2)). The term ***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 persons 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 FD&C Act). Accordingly, growers of tobacco, tobacco warehouses, and tobacco grower cooperatives are not subject to the requirements of part 1140, which is deemed to have been issued under Chapter IX of the FD&C Act.

4. What Is Point of Sale?

The term ***point of sale*** means "any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption."[19] 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). For example, 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.

[19] § 1140.3(g).

VI. PART 1140, SUBPART B — PROHIBITION OF SALE AND DISTRIBUTION TO PERSONS YOUNGER THAN 18 YEARS OF AGE

Subpart B, "access" restrictions, contains four sections:

- § 1140.10, which explains general responsibilities of manufacturers, distributors, and retailers;
- § 1140.12, which explains additional responsibilities of manufacturers;
- § 1140.14, which explains additional responsibilities of retailers; and
- § 1140.16, which explains conditions of manufacture, sale and distribution.

The sections in subpart B 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.

A. Section 1140.10 — General Responsibilities of Manufacturers, Distributors, and Retailers

The regulations in § 1140.10 state that each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco products it manufactures, distributes, labels, packages, advertises, sells, or otherwise holds for sale comply with all applicable regulatory requirements. Retailers, manufacturers, and distributors who are responsible for an item that violates the regulations should remove the violative item or product.

This section is intended to remind parties that they must meet their regulatory obligations under 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. In addition, you may consider:

- 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:

1. ***Am I responsible as a manufacturer if I know that a 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).

2. ***Is a retailer in violation of the regulations if it distributes free samples of smokeless tobacco in his establishment 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,"[20] 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).

B Section 1140.12 — Additional Responsibilities of Manufacturers

The regulation in § 1140.12 imposes an additional responsibility on manufacturers. Under this provision, a manufacturer must remove, from each point of sale (including retail locations), 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 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 a facility where no person under age 18 is present, or permitted to enter, at any time. See section VI.G of this guidance for a more detailed discussion of the exception in §1140.16(c).

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

1. ***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.

2. ***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 include, among others:

[20] See section VI.H of this guidance for the definition of "qualified adult-only facility" and for additional information.

- physically removing the noncompliant display from the premises; or
- altering the display so that it does not violate the regulations. For example, the manufacturer could move the display (with the retailer's permission) so that a person cannot access a product without a retailer's help[21].

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

The manufacturer must remove any advertising, labeling, or other items that fail to comply with the requirements in Subpart D — Labeling and Advertising.[22]

For example:

- the manufacturer cannot market, license, sell, or distribute, or cause to market, license, sell, or distribute, nontobacco items (e.g., tee shirts and hats) or services which 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)).

4. 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 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 addition, FDA will be conducting compliance check inspections and may notify you of a violation.

5. 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 think that an item owned by another company violates the law or regulations, you may contact FDA about the potential violation as described in section IX of this guidance. If FDA determines that the item is violative, the Agency can take appropriate action with respect to the manufacturer that owns the item.

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

[21] See section VI.G of this document, *Section 1140.16(c) — Vending Machines, Self-Service Displays, Mail Order Sales, and Other "Impersonal" Modes of Sale*

[22] As noted in section II of this guidance, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found §§1140.32(a) and 1140.34(b) to be unconstitutional under the First Amendment (see *Discount Tobacco. v. United States*.) Therefore, FDA will not seek to enforce these provisions.

If you fail to remove a violative item that you own, FDA may find your cigarettes and smokeless tobacco products to be misbranded. Among other things, the FD&C Act specifically prohibits misbranding a tobacco product after shipment in interstate commerce as well as the introduction of a misbranded product into interstate commerce. This means that FDA may take regulatory and enforcement actions against you, including:

- seeking civil money penalties;
- seizing your product;
- seeking an injunction against you; or
- criminal prosecution.

C. Section 1140.14 — Additional Responsibilities of Retailers

If you are a retailer, § 1140.14 specifies additional obligations, including:

- not selling cigarettes or smokeless tobacco to anyone younger than 18 years of age;
- verifying that any person buying cigarettes or smokeless tobacco is at least 18 years old or older by means of photographic identification containing the bearer's date of birth for all individuals under the age of 27;
- selling 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,[23] except in limited circumstances. See discussion regarding § 1140.16(c) in section VI.G of this guidance for a more detailed discussion of this exception;
- not breaking 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; and
- removing any violative self-service displays, advertising, labeling, and other items that are in the retail facility.

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

1. 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, these federal regulations do not affect state or local laws relating to access to tobacco products that are in addition to, or more stringent than, the federal access provisions. 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.

[23] 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 44396 at 44451, comment 69).

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

The FDA regulations do not directly address the age of the sales clerk. However, to qualify as a facility where individuals under 18 years of age are neither present, nor permitted to enter at any time for purposes of having vending machines or self-service displays, all clerks in the facility would need to be 18 years of age or older. Additionally, 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.

3. 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 cigarettes or smokeless tobacco to anyone younger than 18 years of age, even if that child has a note from a parent or other adult.

4. 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 manufacturers, distributors, and retailers. However, some states and localities impose penalties on underage children for purchasing, possessing, or using tobacco products.

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

Yes. This would be a photographic identification containing the owner's date of birth.

6. 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.

7. Why did FDA decide that retailers must require all customers who are under the age of 27 to present a photographic identification?

Research has shown that it is very difficult for retailers to accurately determine the age of a customer and that 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,[24] 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.[25]

8. What are some examples of FDA-recommended age verifying techniques?

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.

Below are a few examples of age verifying techniques that retailers may choose to implement to assist employees in verifying a purchaser's age:

- Requiring employees to compare the date of birth on the photographic identification with a calendar that displays the most recent date that can be shown

[24] 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.

[25] Id.

on the photographic identification in order for that person to purchase cigarettes and smokeless tobacco;

- Installing price scanners that are programmed so that when a tobacco product is scanned, the register displays a message prompting the employee either to request age identification and key in the purchaser's date of birth or to verify that the purchaser is over 18 years old; and
- Requiring employees to scan all photographic identifications through an electronic age verification device.

9. What should a retailer or his employee do when he or she suspects a customer's identification is fake, altered, or insufficient?

If a retailer or his employee suspects that an ID is unreliable, he or she 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 is valid.

10. 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 under federal law?

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.

11. May retailers use internal compliance check or mystery shopper programs to test compliance with part 1140?

Yes. Retailers are encouraged to implement an internal check program, also known as a mystery shopper program. In this type of program, retailers use either a person of legal age who is younger than 27 years old (to test whether clerks are requesting photographic identification) or a person who is under the legal age (to test whether clerks are both requesting photographic identification and refusing to make a sale to underage youth) to buy cigarettes or smokeless tobacco. FDA does not intend to bring enforcement action under §1140.14(a) or (b) for purchases made under these programs. Please also refer to the guidance for industry on *Tobacco Retailer Training Programs* for additional information.

12. 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.

13. Can I sell single cigarettes?

No, in most cases.[26] In accordance with §§ 1140.14(d) and 1140.16(b), you may not sell individual cigarettes (often called "singles" or "loosies") or any package with less than 20 cigarettes, or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use. 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 quantities of cigarette tobacco or smokeless tobacco smaller than the smallest package distributed by the manufacturer for individual consumer use, are generally cheaper than a full sized pack of cigarettes, or a package of cigarette tobacco or smokeless tobacco for individual consumer use, and, as a result, may entice children and adolescents to try using these products. Section 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 in facilities[27] where no person younger than 18 years of age is present, or permitted to enter, at any time.

14. 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(d), 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.

15. What is the retailer's responsibility concerning point-of-sale displays, advertising, labeling, and other items?

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.

Note that the regulations also require manufacturers to remove items that they own if those items violate the regulations.

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[26] See § 1140.16(c)(2)(ii) concerning the limited exception to sell packaged, individual cigarettes in vending machines located in facilities where no person younger than 18 years of age is present, or permitted to enter, at any time.

[27] See § 1140.16(c) clarifying facilities in which vending machines and self-services displays are permitted.

16. Who determines if a violative item is owned by the manufacturer when there is a question as to who owns the violative self-service display, advertising, labeling, or other item?

It may not be easy to determine who is responsible for the self-service display, advertising, 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 (§ 1140.14(e)). Thus, when there is a question to whether the retailer or manufacturer is the owner of a violative item at a point of sale, under the regulations, the retailer has the responsibility to ensure that all self-service displays, advertising, labeling and other items in its establishment comply or are brought into compliance. This is the retailer's responsibility whether or not the manufacturer also has some responsibility for the item.

17. Am I responsible for the actions of my employees?

Yes. Employers are responsible for their employees' actions.[28] This is true even if the employer does not know about the employee's actions or the employee fails 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 prohibit 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. 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. If your state or local government has additional requirements, you may add them to your training program as well.

D. Section 1140.16 — Conditions of Manufacture, Sale, and Distribution

Section 1140.16 includes several different regulatory requirements. Some apply only to manufacturers (such as the restriction on product names), some apply only to retailers (such as the restriction on "impersonal" modes of sale), and others apply to manufacturers, distributors, and retailers (such as the requirement for maintaining a minimum package size for cigarettes).

[28] *See, e.g., U.S. v. Dotterweich*, 320 U.S. 277 (1943) (holding that a corporate official is liable for his company's violations of the FD&C Act, 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).

E. Section 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.

On May 7, 2010, after FDA became aware of concerns regarding this provision, FDA announced the availability of the guidance entitled *Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco*. The guidance discusses FDA's enforcement discretion policy concerning § 1140.16(a). Specifically, the guidance provides that FDA, while considering what changes to the regulation, if any, would be appropriate, intends to exercise its enforcement discretion concerning § 1140.16(a) not to begin enforcement actions under this provision in cases 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 nontobacco product bearing the same name; provided, however, that the tobacco and nontobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities (including as a licensee).[29]

On November 17, 2011, FDA published a proposal to amend § 1140.16(a).[30] In that proposal, FDA noted that it was aware of concerns raised by the current rule, including its constitutionality, and that, after considering those concerns, it was proposing to narrow the scope of the rule. As of the date of this guidance, the proposal is pending and FDA's enforcement discretion policy in its 2010 guidance is still in effect.

F. Section 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 packages sold in the United States contain 20 cigarettes. If you distribute or sell cigarette packages 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 packages, 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 packages. (Cigarette prices are a critically important tool in reducing adolescent smoking beyond experimentation.)[31] As a result, FDA specifies a minimum cigarette

[29] 75 FR 25282 (May 7, 2010).
[30] 76 FR 71281 (November 17, 2011).
[31] See Emery, Sherry, et al., "Does cigarette price influence adolescent experimentation?" *Journal of Health Economics*, vol. 20, pp. 261-270, 2001.

package 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:

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

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

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

2. ***Is there a minimum package size for smokeless tobacco or cigarette tobacco?***

   The regulations do not contain a minimum package size for smokeless tobacco or cigarette tobacco. However, retailers may not break or otherwise open a cigarette or smokeless tobacco package to sell any quantity of smokeless tobacco or cigarette tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use (§ 1140.14(d)). For example, retailers may not open the original manufacturer's package of smokeless tobacco and cigarette tobacco and sell a portion of it to consumers in smaller cups, bags, or other containers.

3. ***Is there any exception to the minimum cigarette package size?***

   There is a very limited exception for packaged, single cigarettes sold in vending machines that are located in facilities where no one younger than 18 years of age is present, or permitted to enter, at any time (§1140.16(c)(2)(ii)).

G. Section 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 only in a direct, face-to-face exchange, subject only to limited exceptions, as described below. This section reinforces this requirement by prohibiting retailers from engaging in "impersonal" modes of sale.

The two limited exceptions are:

- Mail order sales are acceptable under these regulations,[32] except that mail-order redemption of coupons and distribution of free samples through the mail are not permitted.[33]

[32] See the preamble to "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," 61 FR 44396 at 44435, 44438, 44458-44459 (August 28, 1996), which discusses FDA's reasoning behind not prohibiting mail order sales.

- 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. The purpose of this exception is to allow retailers to use vending machines and self-service displays as long as they ensure that no person younger than 18 years of age is present in their facility or permitted to enter at any time.

Some commonly asked questions relating to this section include:

1. 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 cigarettes and smokeless tobacco products getting into the hands of children.

2. What is a "self-service display" under the regulations?

A self-service display is any item that permits a consumer to access and remove cigarettes or smokeless tobacco products without a direct, face-to-face exchange between the retailer and the customer. Self-service displays, which also may be referred to as "merchandisers," come in many different shapes and sizes, ranging from free-standing, multishelf 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 a permissible method of selling cigarettes or smokeless tobacco in any facility (e.g., pharmacy, convenience store, grocery store, gas station, restaurant) where anyone younger than 18 years of age is present, or permitted to enter, at any time. So, if anyone younger than 18 years of age is present in, or is permitted to enter, your retail facility at any time, you cannot use self-service displays and vending machines to sell cigarettes or smokeless tobacco products.

To qualify as a facility where individuals under 18 years of age are neither present nor permitted to enter at any time for purposes of having vending machines or self-service displays, all employees in the facility would need to be 18 years of age or older.

[33] The regulations permit mail-order sales of cigarettes and smokeless tobacco (§ 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 and Title 18 to revise provisions governing the collection of taxes on, and trafficking in, cigarettes, including roll-your-own cigarettes, and smokeless tobacco. Among other requirements, the PACT Act requires the U.S. Postal Service (USPS), subject to certain narrowly defined exceptions, 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.

3. Can I keep vending machines (including vending machines that sell packaged, single cigarettes) or self-service displays in my retail facility that allows anyone younger than 18 years of age to be present or permitted to enter if I supervise or lock the machine or display?

No. The regulation prohibits all "impersonal" modes of sale for cigarettes and smokeless tobacco products with limited exceptions. Simply supervising a self-service display or vending machine, or using electronic locks, tokens, remote operating mechanisms, or taking other actions that continue to give customers an opportunity to access and remove cigarettes or smokeless tobacco products without a direct, face-to-face exchange between the retailer and the customer is not permitted because these would be considered "impersonal" modes of sale. These means of limiting access of self-service displays and vending machines are often ineffective when it comes to preventing children and adolescents from accessing cigarettes or smokeless tobacco. [34]

If you are a retailer, the regulations require you to hand the product to the customer in a direct, face-to-face exchange with limited exceptions. For example, if your retail store allows anyone younger than 18 years of age to be present, or permitted to enter, at any time and you would like to use a display that holds cigarette packages, you cannot keep that display on the counter or anywhere else accessible to customers if the customer can take the cigarettes without a direct, face-to-face exchange between you and the customer. It does not matter whether you can see the customer choose the cigarettes or whether the customer has to "ask permission" to buy the cigarettes. If you would like to keep the display, you can move it behind the counter to an area where customers are not permitted to enter, thus maintaining a direct, face-to-face exchange between the retailer and the customer and eliminating the "self-service" aspect of the display. Alternatively, you can restrict access to your facility and ensure that no person younger than 18 years of age is present or permitted to enter at any time, as described in the question below.

4. What types of facilities may qualify to use vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays within the meaning of § 1140.16(c)(2)(ii)?

To be considered a facility that can use vending machines and self-service displays to sell cigarettes and/or smokeless tobacco without a face-to-face exchange, no person under the age of 18 may be present, or permitted to enter, *at any time* (emphasis added). However, there may be situations where an area may be treated as including two separate facilities, where one has access restrictions at all times, while the other allows individuals younger than 18 years of age to be present, or permitted to enter, at least some times. In the examples below, vending machines or self-service displays may be in the area that restricts access at all times, but may not be in the area that allows individuals younger than 18 years of age to be present, or permitted to enter, at least some times.

- You own a factory that has 10 buildings on the factory grounds, but you want to put a cigarette vending machine in one building. You would only be expected to

[34] See 61 FR 44396 at 44450, comment 68, and 44451, comment 69.

keep people younger than 18 years of age from being present, or permitted to enter at any time, in the building that contains the vending machine.

- 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 permitted to enter at any time, in your store in order to qualify for the exception. You would not be responsible for ensuring that people younger than 18 are prevented from entering the rest of the building.

- A restaurant that allows people of all ages to be present, or permitted to enter, is on one floor of a casino. On a separate floor with access restrictions, there is a vending machine. In order for this to be permitted, means should be in place between the floors, for example someone checking identifications, to ensure that no one younger than 18 years of age is present, or permitted to enter, at any time.

- A private club has a hall that is rented to the general public of all ages and a separate members-only area that prohibits anyone younger than 18 years of age to be present, or permitted to enter, at any time with a vending machine. In order for this to be permitted, means should be in place to restrict access to the members-only area. For example, the door to the members-only area should be locked and only adult members, whose age and identification are verified before being permitted to enter, have a key. Minors, including family members, would not be allowed to be present, or permitted to enter, in the members-only area at any time.

- An area of a retail store is physically separated from the rest of the store by a door or gate. The retailer may have a self-service display or vending machine in the area of the store that is physically separated from the rest of the store if it has measures in place that ensure that no one younger than 18 years of age is allowed to be present, or permitted to enter, in the restricted area at any time.

In contrast, an example of noncompliance with § 1140.16(c):

- A restaurant with a bar that does not implement restrictions to ensure that no one under 18 years of age is present, or permitted to enter, the bar area at any time. A vending machine in any part of the restaurant, including the bar, would be a violation of this section. Having a bartender watch the vending machine would be insufficient without additional measures to restrict access to all minors at all times.

5. What measures can be implemented to ensure that no person younger than 18 years of age is present, or permitted to enter, at any time?

The regulations do not specify how you should prevent people younger than 18 years of age from being present in, or permitted to enter, your facility if your facility has vending machines or self-service displays for cigarettes and/or smokeless tobacco. It is up to the

retailer to determine how best to comply with the requirements based on the individual retail establishment. Multiple measures are highly recommended as a single measure may not be sufficient to ensure compliance. Regardless of the measure(s) you use, if you want to qualify for the exception, it is important that no one younger than 18 years of age is present in, or permitted to enter, the facility *at any time*.

Examples of measures may include, but are not limited to:

- an employee to check for proof of age at the door at all times — a customer 18 years of age or older is permitted to enter the facility; however, a customer younger than 18 years of age is barred from entering;
- a locked gate or barrier that separates the public area of the store from the adult- only area; and
- an establishment with an internal room that implements means to ensure that only customers who are 18 years of age or older can enter.

6. Who is responsible for a vending machine in a facility?

FDA recognizes that the person who owns/operates 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 to be held responsible for complying with the requirements.

7. Can I let people younger than 18 years of age into my facility only on special occasions and still legally have a vending machine or self-service display?

Facilities, such as clubs or recreation halls, that are "off limits" to people younger than 18 years of age most of the time, but that are occasionally rented for parties or other social events where people younger than 18 years of age may be present, or permitted to enter, do not qualify for the exception. Vending machines and self-service displays for cigarettes or smokeless tobacco are permitted only in facilities where no one younger than 18 years of age can be present in, or be permitted to enter the facility at any time, even on special occasions.

8. Can I qualify for the exemption if I let individuals under 18 years of age into my facility only when accompanied by their parents?

No. If the facility has a vending machine or self-service display for cigarettes or smokeless tobacco, no one younger than 18 years of age, including infants and small children accompanied by their parents, can be present, or be permitted to enter, in the facility at any time.[35]

[35] Please see question 5 above for additional information on measures that a retailer can take to fall within the exception.

H. Section 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 a date of birth indicating the holder is at least 18 years of age (state law may require persons to be older than 18 in some states);
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 youth-oriented marketing, promotional, or other activities;
4. is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose 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 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);
    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.

The regulation, however, prohibits manufacturers, distributors, or retailers from distributing or causing to be distributed any free samples of smokeless tobacco:

- to a sports team or entertainment group; or

- at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by § 1140.16(d)(3).

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

1. 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 products in limited quantities, but only in a qualified adult-only facility.

2. 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).

3. What are the restrictions on distribution of free samples of cigarettes and smokeless tobacco products when using rebates or redeeming coupons by mail or from a retail outlet?

Under § 1140.16(d)(1), manufacturers, distributors, and retailers may not distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco, except as provided under § 1140.16(d)(2). Therefore, rebates or coupons cannot be used as a means to distribute free samples of cigarettes and smokeless tobacco products by mail. In addition, coupons for free samples of cigarettes or smokeless tobacco that do not require purchase cannot be redeemed at a retail outlet.

Note that mail-order redemption of coupons and distribution of free samples of cigarettes or smokeless tobacco through the mail are prohibited under § 1140.16(c)(2)(i).

I. Section 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 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 FD&C Act, and selling or distributing misbranded products 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 FD&C Act, this may lead to regulatory action against you.

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, ask for products that comply with the regulations, and contact FDA to report the violation.

VII. PART 1140, SUBPART D — LABELING AND ADVERTISING

Subpart D on labeling and advertising contains three sections:

- § 1140.30 Scope of permissible forms of labeling and advertising;
- § 1140.32 Format and content requirements for labeling and advertising; and
- § 1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

A. Section 1140.30 — Scope of Permissible Forms of Labeling and Advertising

Section 1140.30(a)(1) describes the forms of labeling and advertising that are permissible under the regulations without prior notice to FDA. A manufacturer, distributor, or retailer can disseminate labeling and advertising that bears a cigarette or smokeless tobacco brand name (or any other indicia of tobacco product identification) without prior notice in or on the following media:

- newspapers;
- magazines;
- periodicals or other publications (whether periodic or limited distribution);
- billboards, posters, and placards;
- non-point-of-sale promotional material (including direct mail);
- point-of-sale promotional material; and
- audio or video formats delivered at a point of sale.

Section 1140.30(a)(2) requires that 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 above notify the Agency 30 days prior to the use of such medium. The notice must describe the medium intended to be used 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 must send this notice to the Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration.

In the preamble to the "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" published in 1996, FDA stated that online media are not included within the list of permissible outlets and that advertisers should notify the Agency under § 1140.30(a)(2) prior to advertising on the Internet (61 FR 44396 at 44502). FDA also stated in the preamble that product placements in movies, music videos, and television, if not done at the expense of tobacco manufacturers, distributors, or retailers, would not be affected by this rule (61 FR 44396 at 44501).

Online and other electronic media are not listed in the permissible forms of advertising without prior notice under § 1140.30(a)(1). Therefore, CTP expects manufacturers, distributors, or retailers engaging in tobacco product advertising through media not listed in § 1140.30(a)(1), including online media, to notify the Agency 30 days prior to using such media, as required by § 1140.30(a)(2). Forms of electronic and online media that require notification under § 1140.30(a)(2) include but are not limited to:

- Internet Web sites
- Product placements in movies, music videos, and television, if done at the expense of tobacco manufacturer, distributor, or retailers
- Blogs or weblogs (e.g., Blogger, WordPress, Tumblr)
- Emails sent to consumers
- Microblogs (e.g., Twitter)
- Podcasts (e.g., audio sharing)
- Social networks and online communities (e.g., Facebook, MySpace, LinkedIn, Friendster)
- Video sharing (e.g., YouTube, Blip tv, Vimeo)
- Widgets or window gadgets
- Wikis (e.g., Wikipedia)
- Applications for smart phones and tablet computers (e.g., iPhones, Androids, iPads)
- Text messaging
- Instant messaging
- Pop up or roll-over advertisements on Web sites

Manufacturers, distributors, and retailers must provide the notification required by § 1140.30(a)(2) for each medium through which they plan to disseminate, or cause to be disseminated, advertising and labeling. If any previous access restrictions are modified such that advertising or labeling previously unseen by persons younger than 18 years of age may then be seen by persons younger than 18 years of age, the regulated entity should submit a new notification under § 1140.30(a)(2). If a regulated entity plans to disseminate product labeling or advertising for regulated tobacco products in a medium not listed under § 1140.30(a)(1), the entity must provide the notification required by § 1140.30(a)(2) at least 30 days prior to the use of such medium.

The notification provided under § 1140.30(a)(2) is not intended to imply that prior approval is required.

Notification to FDA can be securely transmitted via the CTP Portal using the eSubmitter tool.[37]

[37] Information about the CTP Portal can be found at: https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal. Additional information about the eSubmitter tool can be found at: https://www.fda.gov/industry/fda-esubmitter/esubmitter-tutorial-videos. Alternatively, the FDA's Electronic Submission Gateway (ESG) is still available as an option to the CTP Portal. Please refer to the ESG website instructions for setting up a WebTrader account at https://www.fda.gov/industry/create-esg-account/setting-webtrader-account-checklist

Alternatively, you may send the notification via U.S. Mail or courier to the following address:

Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Notification Components:

1. Cover letter

To facilitate FDA's review of media notifications, FDA requests that your notification be accompanied by a cover letter that includes:

- Date of the notification;
- The following subject lines:

  "RE: § 1140.30(a)(2) Notification of Other Advertising and Labeling Medium";
- The official contact name, address, email, fax number and phone number of the person authorized to act as the FDA contact regarding the notification.
- The name of the most responsible individual of the regulated entity, if the submitter is an agent submitting on behalf of the regulated entity;
- An indication whether the notification is done by or on behalf of a manufacturer, distributor, or retailer of the tobacco products covered by the submission.

2. Information to include in the submission under § 1140.30(a)(2)

The notification should include the following information:

- A list of the tobacco products covered by notification;
- A detailed description of the advertising or labeling medium;
- A discussion of the extent to which the advertising or labeling medium may be seen by persons younger than 18 years of age; and
- A discussion of any access restrictions, including restrictions for persons younger than 18 years of age to the advertising or labeling medium.

Section 1140.30(c) states that subpart D of the regulation does not apply to cigarette or smokeless tobacco package labels.

B. Section 1140.32 — Format and Content Requirements for Labeling and Advertising

On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found § 1140.32(a) to be unconstitutional under the First Amendment. (See *Discount Tobacco v. United States*.) Therefore, FDA will not seek to enforce this provision.

C. Section 1140.34 — Sale and Distribution of Nontobacco Items and Services, Gifts, and Sponsorship of Events

Section 1140.34 establishes prohibitions on the following forms of promotions:

- any items (other than cigarettes, smokeless tobacco, or roll-your-own paper) or services, which bear the tobacco 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; and
- 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.

D. Section 1140.34(a) — Nontobacco Items and Services

The regulations establish restrictions on promotional items and services. This provision applies to all manufacturers and to distributors of imported products. If you are 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 item (other than cigarettes, 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 that is the same as or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

E. Section 1140.34(b) — Gifts

On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found §1140.34(b) to be unconstitutional under the First Amendment. (See *Discount Tobacco v. United States*.) Therefore, FDA will not seek to enforce this provision.

F. Section 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 the sponsorship is 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 of 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 may not sponsor a basketball tournament if it would call the tournament the "BRANDNAME Cigarette Tournament" or sponsor the tournament in the name "BRANDNAME Cigarettes." The manufacturer also may not 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 both the corporate name and the corporation were registered and in use in the United States before January 1, 1995, and the corporate name itself does not include 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 were 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.

VIII. EFFECTIVE DATE FOR THE REGULATIONS

These regulations were published on March 19, 2010, and became effective on June 22, 2010. This enabled manufacturers, distributors, and retailers to take whatever steps they needed to settle their existing business affairs, to adjust their 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 described in this guidance, FDA intends to exercise enforcement discretion with respect to § 1140.16(a). In addition, FDA will not seek to enforce §§ 1140.32(a) and 1140.34(b).

A. Section 1140.16(a)

Under this section of the 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. As discussed above, on November 17, 2011, FDA published a proposal to amend this provision, entitled "Restrictions on the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.[38]

While FDA considers what changes, if any, would be appropriate, it intends to exercise its enforcement discretion concerning § 1140.16(a) not to bring enforcement actions under this provision for the duration of its consideration in cases where:

- 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

- 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 nontobacco product bearing the same name provided, however, that the tobacco and nontobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities (including as a licensee).[39]

B. Sections 1140.32(a) and 1140.34(b)

On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found §§ 1140.32(a) and 1140.34(b) to be unconstitutional under the First Amendment. (See *Discount Tobacco v. United States*.) Therefore, FDA will not seek to enforce these provisions.

IX. HOW TO REPORT VIOLATIONS TO FDA

Members of the general public can report potential tobacco product violations to FDA's Center for Tobacco Products via:

- online (https://www.accessdata.fda.gov/scripts/ptvr/index.cfm)
- email (ctpcompliance@fda.hhs.gov);
- phone (1-877-CTP-1373); or
- mail (Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue Silver Spring, MD 20993-0002).

[38] See 75 FR 25271 (May 7, 2010).
[39] See 75 FR 25271 (May 7, 2010).

X. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.3501-3520).

The time required to complete this information collection is estimated to average 25 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Food and Drug Administration Center
for Tobacco Products Document
Control Center Building 71, Room
G335 10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0312 (To find the current expiration date, search for this OMB control number available at https://www.reginfo.gov).

XI. DOCUMENT HISTORY

August 2013 – Guidance is published.

November 2022 –

- Added the OMB control number information on the cover page and section X, Paperwork Reduction Act of 1995, of this guidance.
- Updates to hyperlinks for electronic copies of this guidance.
- eSubmitter was added as an alternative method to transmit notifications under § 1140.30(a)(2) electronically.

Attachment 1 — Regulation References

Who Is Subject to the Regulations	Regulation Section	Where I Can Find This Information in This Guidance Document?
Manufacturers, Distributors, and Retailers	1140.10 – General Responsibilities	See section VI.A
Manufacturers	1140.12 – Additional Responsibilities of Manufacturers	See section VI.B
Retailers	1140.14 – Additional Responsibilities of Retailers	See section VI.C
Manufacturers, Distributors, and Retailers	1140.16 – Conditions of Manufacture, Sale, and Distribution	See section VI.D
Manufacturers, Distributors, and Retailers	1140.30 – Permissible Labeling and Advertising	See section VII.A
Manufacturers, Distributors, and Retailers	1140.34 – Sale and Distribution of Nontobacco Items and Services, Gifts, and Sponsorship of Events	See section VII.C