The Prohibition of Distributing Free Samples of Tobacco Products

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
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Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to help tobacco product manufacturers, distributors, and retailers understand the prohibition of distributing free samples of tobacco products set forth in Title 21, Code of Federal Regulations (CFR), Part 1140 and to explain what you should do in order to comply with the regulations. The document explains, among other things, what activities and which persons are subject to the regulations, as well as how the prohibition of distributing free samples applies to the distribution of tobacco products through:

- non-monetary exchanges;
- membership and rewards programs;
- contests and games of chance; and
- business-to-business exchanges.

FDA is requesting public comments regarding its interpretation of the free sample ban set forth in this guidance. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

[1] This guidance was prepared by the Office of Compliance and Enforcement and Office of Regulations in the Center for Tobacco Products at FDA.

FDA's guidance documents, 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 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, amended the Food, Drug, and Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate tobacco products. Section 102 of the Tobacco Control Act required FDA to reissue the final regulations regarding cigarettes and smokeless tobacco promulgated by FDA in 1996 (Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (1996 final regulations)),[2] 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 480,000 deaths each year.[3] 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."[4] 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.[5]

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.[6]

On March 19, 2010, FDA published its final regulations, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," at 21 CFR Part 1140. This rule contains a number of provisions restricting the marketing, sale, and distribution of tobacco products aimed at limiting youth access to tobacco products. Among other requirements, the regulations prohibit:

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[2] *See* 61 FR 44396 (Aug. 28, 1996).

[3] *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 -- 50 Years of Progress: a Report of the Surgeon General, 2014.

[4] Section 2(15) of the Tobacco Control Act.

[5] *See* sections 2(1), (26), (30)-(32) of the Tobacco Control Act.

[6] *See* Congressional Record, S6407, June 10, 2009, Statement of Senator Kennedy.

- The distribution of free samples of tobacco products, except for smokeless tobacco distributed in "qualified adult-only facilities" in accordance with the regulations;[7]
- The sale of cigarettes and smokeless tobacco to individuals under 18 years of age; and
- The sale of cigarettes and smokeless tobacco to individuals under 27 years of age without verifying by means of photographic identification that the purchaser is at least 18 years of age.

At the time, the regulations applied to cigarettes, including roll-your-own tobacco; cigarette tobacco; and smokeless tobacco products.

On August 8, 2016, the "deeming provisions" of FDA's "Deeming Rule" became effective.[8] These provisions expanded FDA's tobacco product authority to include all products meeting the statutory definition of a tobacco product, except for accessories of newly deemed tobacco products. Thus, the ban on distributing free samples applies to all tobacco products that are subject to FDA's tobacco product authority, and the minimum purchase age and the identification verification requirements apply to covered tobacco products. In deeming these additional tobacco products subject to FDA's tobacco product authorities, FDA noted reports that free samples of these products were easily and freely accessible by youth, with reports of e-cigarettes being distributed at venues likely to attract large audiences and youth oriented events, such as music festivals and motorsports events.[9]

III. DISCUSSION

A. Definitions

Component or part: The term component or part[10] is defined in 21 CFR § 1140.3 and means any software or assembly of materials intended or reasonably expected:

(1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) to be used with or for the human consumption of a tobacco product.

Component or part excludes anything that is an accessory[11] of a tobacco product.

[7] Note that, separately from the free sample ban, the FD&C Act prohibits the charitable distribution of tobacco products. *See* FD&C Act § 301(rr).

[8] *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 FR 28974 (May. 10, 2016).

[9] *Id*. at 28986

[10] FDA notes that component and part are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of 21 CFR Part 1140 and this guidance, FDA is using the terms component and part interchangeably and without emphasizing the distinction. FDA may clarify the distinctions between component and part in the future.

[11] The term "accessory" means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets

Covered tobacco product: The term covered tobacco product is defined in 21 CFR § 1140.3 and means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under 21 CFR § 1100.2, but excludes any component or part that is not made or derived from tobacco.

Distributor: The term distributor is defined in 21 CFR § 1140.3 and means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of 21 CFR Part 1140.

Finished tobacco product: The term finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).

Manufacturer: The term tobacco product manufacturer is defined in 21 CFR § 1140.3 and means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product.

Retailer: The term retailer is defined in 21 CFR §1140.3 and means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under 21 CFR Part 1140.

Tobacco product: The term tobacco product is defined in section 201(rr) of the FD&C Act, which states in relevant part:

> (1) The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).
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> (2) The term "tobacco product" does not mean 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 described in section 503(g) of the FD&C Act.

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either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) Solely controls moisture and/or temperature of a stored product; or (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Note that this definition includes accessories and components and parts of tobacco products that are subject to Chapter IX of the FD&C Act, whether they are made or derived from tobacco and whether they are sold or distributed as finished tobacco products.[12]

B. The Free Sample Ban

The free sample ban is codified at 21 CFR § 1140.16(d)(1), which states, "Except as provided in [21 CFR § 1140.16(d)(2)], no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act)."

The exception described in 21 CFR § 1140.16(d)(2) allows for the distribution of free samples of smokeless tobacco products in "qualified adult only facilities," i.e., facilities that meet a number of specific requirements, such as verifying that all customers are at least 18 years of age. The focus of this guidance is free samples that are not distributed in a "qualified adult only facility."

C. Tobacco Products Subject to the Free Sample Ban

The free sample ban prohibits the distribution of free samples of "cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act)."[13] This means that the free sample ban automatically applies to all tobacco products subject to FDA's tobacco product authority, including components and parts of tobacco products, except smokeless tobacco product samples distributed in "qualified adult only facilities" in accordance with 21 CFR § 1140.16(d)(2).

Unlike other restrictions that the Deeming Rule expanded to include only "covered tobacco products" (i.e., deemed tobacco products made or derived from tobacco) [14] or provisions that FDA intends at this time to enforce only against "finished tobacco products,"[15] the free sample ban applies to *all* tobacco products that are subject to FDA's tobacco product authority, even if they are not made or derived from tobacco. This means that the free sample ban prohibits manufacturers, distributors, and retailers from giving out free samples of any tobacco product that is subject to FDA's tobacco product authorities, including components and parts of tobacco products, such as atomizers, clearomisers, and e-liquids. This is an important restriction because components and parts of some tobacco products, such as the aerosolizing apparatus of e-cigarettes, can be the most expensive part of a tobacco product. If minors can obtain the most expensive components or parts of tobacco products as free "samples," they face less significant barriers to using tobacco products.

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[12] However, accessories of newly deemed products are not subject to the deeming rule. Thus, although such accessories meet the definition of tobacco product, they are not currently subject to regulation under Chapter IX of the FD&C Act.

[13] 21 CFR § 1140.16(d)(1).

[14] *E.g.*, 21 CFR § 1140.14(b).

[15] *See e.g.*, 81 FR 28974 at 28995 ("However, at this time, FDA intends to limit enforcement of the premarket authorization provisions to finished tobacco products.").

D. Tobacco Products Must Be Sold to Consumers

As discussed in the 1996 final regulations preamble and reiterated in the preamble to the Deeming Rule, the distribution of free samples presents a "risk free and cost free" source of tobacco products for youth[16] and frequently occurs in situations that limit the free sample distributor's ability to request proof of age.[17] By prohibiting the distribution of free samples of tobacco products, FDA (and later Congress, by directing FDA to reinstate this portion of the 1996 rule) eliminated this source of tobacco products for youth by requiring tobacco products to be distributed only through product sales[18] that, through other parts of the rule reinstated in 2010, are subject to minimum purchase age and photographic identification verification requirements.[19] The free sample ban and these requirements work together to advance the government's interest in reducing youth access to tobacco products. This means that manufacturers, distributors, and retailers may distribute tobacco products to consumers only through a tobacco product sales transaction.

E. Monetary Payment is Required for Tobacco Product Sales

In a 2012 decision that upheld the free sample ban against a First Amendment challenge, the Sixth Circuit Court of Appeals observed that creating opportunities for youth "to actually try a tobacco product, at no cost, may serve as the best advertisement of all for a product that is physiologically addictive, and socially attractive to youth."[20] By implementing the free sample ban for the primary purpose of eliminating an "easily accessible source of these products to young people,"[21] the FDA regulations require that consumers face a monetary cost in order to receive a tobacco product. This means that retailers must charge consumers money for tobacco products and may not, for example, distribute tobacco products in exchange for providing contact information or signing up for a mailing list. While contact information may have value to manufacturers, distributors, or retailers, providing this information comes at no financial cost to the consumer and could be a "risk free and cost free" source of tobacco products for youth. Therefore, distributing a tobacco product in exchange for something non-monetary, such as a consumer's contact information, is a prohibited free sample.

While the free sample ban does require that manufacturers, distributors, and retailers distribute tobacco products to consumers only through tobacco product sales transactions and only in exchange for money, there are situations in which the sale of tobacco products to consumers at less than full price does not violate the ban. The following examples describe FDA's current

[16] 61 FR 44396 at 44460.
[17] *Id*.
[18] *See id.* (stating, "the agency agrees that [the free sample ban] will affect adults by effectively requiring them to purchase cigarettes and smokeless tobacco rather than receive them free of charge" and "the final rule does not alter an adult's ability to select or purchase cigarettes and smokeless tobacco.").
[19] 21 CFR § 1140.14(a)-(b).
[20] Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 541 (6th Cir. 2012), *cert. denied*, 569 U.S. ___, 133 S. Ct. 1966 (2013).
[21] 61 FR 44396 at 44460, *quoted with approval in* Discount Tobacco City, 674 F.3d at 541.

thinking on how the free samples ban generally applies; however, FDA intends to consider the specific facts of potential violations on a case-by-case basis to determine whether they present a potential "risk free and cost free" source of tobacco products for youth.

1. Coupons and Discounts

The free sample ban does not prohibit manufacturers, distributors, and retailers from selling tobacco products at a discount or accepting coupons that allow consumers to purchase tobacco products at a discount.[22] Promotions such as selling tobacco products at 10% off the regular price or coupons that take dollars or cents off of the purchase price of a tobacco product are not prohibited. Promotions such as "buy one get one free at the time of purchase" or "two for the price of one" are also examples of non-prohibited discounts because they represent a 50% discount off of the sales price of two tobacco products and the "free" tobacco product is received as part of a tobacco product sales transaction.

Promotions that offer consumers a free tobacco product in a separate transaction that is not a tobacco product sales transaction are prohibited where they would allow consumers to obtain a free tobacco product sample and also evade the minimum age and ID requirements. For example, while "buy one pack of cigarettes and get another pack free at the time of purchase" and "two for the price of one" promotions are not banned, a "buy one pack of cigarettes and get a coupon redeemable for a free pack of cigarettes" promotion would be prohibited unless the manufacturer, distributor, or retailer has devised a way to adequately verify that the person redeeming the coupon is the original purchaser, because that coupon would let a consumer, including a minor who was not the original purchaser, obtain a tobacco product outside of a tobacco product sales transaction that requires monetary payment (and is subject to minimum age and ID requirements).

2. Membership and Rewards Programs

Membership and rewards programs that provide discounts to tobacco product purchasers are also not prohibited by the free sample ban as long as they do not result in distribution of tobacco products outside of a tobacco product sales transaction subject to minimum age and ID requirements. Rewards programs that offer a tobacco product as a "reward," such as punch card programs (i.e., get a hole punched in the card for each purchase and receive a tobacco product when all the holes have been punched), are prohibited except where the "reward" is distributed as part of a tobacco product sales transaction that requires monetary payment. For example, if a retailer offered a rewards program in which consumers receive every tenth vial of e-liquid for free, the retailer would not be prohibited from distributing the "free" e-liquid as part of a tobacco product sales transaction (e.g., with the ninth e-liquid purchase or with the eleventh e-liquid purchase), but it could not distribute a free vial of e-liquid to consumers outside of a tobacco product sales transaction that requires monetary payment, unless the manufacturer, distributor, or retailer has devised a way to adequately verify that the person receiving the reward is the original

[22] It is important to note, however, that the mail order redemption of coupons is prohibited under 21 CFR § 1140.16(c)(2)(i).

purchaser. Distributing a "free" tenth vial of e-liquid with either the ninth or eleventh purchase would not violate the free sample ban because it would effectively amount to a discount, not a free sample that is part of a sales transaction requiring monetary payment.

Similarly, membership programs are not prohibited by the free sample ban as long as they do not result in distribution of tobacco products outside of a tobacco product sales transaction that requires monetary payment and is subject to minimum age and ID requirements. The ban would not prohibit a retailer from offering a discount on tobacco product purchases to program members, but it would prohibit the distribution of free tobacco products to members outside of a tobacco product sales transaction that requires monetary payment. For example, the ban would not prohibit the sale of membership to a club that provides a 10% discount on all tobacco product purchases, but a retailer could not sell membership to a club that provides free samples of tobacco products outside of tobacco product sales transactions that require payment of money (and are subject to minimum age and ID requirements).

Again, in determining whether a violation has occurred, FDA would consider whether the manufacturer, distributor, or retailer has devised a way to adequately verify that the person receiving the reward is the member or original purchaser.

3. Contests and Games of Chance

Contests and games of chance are generally not prohibited under the free sample ban; however, similar to other promotions, the contest prize may not be a tobacco product unless it is distributed as part of a tobacco product sales transaction that requires monetary payment and is subject to minimum age and ID requirements. For example, the ban does not prohibit a retailer from allowing customers to enter into a drawing or raffle and give a prize of a tobacco product discount or a coupon redeemable for a "free" tobacco product at the time of another tobacco product purchase, but the retailer could not distribute a free tobacco product as a prize outside of a tobacco product sales transaction that requires monetary payment and is subject to minimum age and ID requirements.

While contests and games of chance that do not result in the distribution of free samples of tobacco products are not prohibited by the free sample ban, manufacturers, distributors, and retailers seeking to have a contest or game of chance with a tobacco product as a prize should be aware that a variety of state and Federal laws restrict how these promotions may be held.

F. Business-to-Business Exchanges

To the extent applicable, FDA does not intend to enforce this regulation with respect to businesses distributing free samples in a limited quantity (i.e., no more than necessary to achieve a business or marketing goal, such as awareness of and exposure to the product for the purposes of product or inventory selection) to another business as part of a genuine effort to sell or market a tobacco product to that business.